

EXHIBIT 19

Confidential Subject to Protective Order



ACTAV 001866996

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION REPORT

DIGOXIN TABLETS, 0.125 mg
1,600,000 TABLETS

BATCHES 4318A, 4320A, and 4322A

MPR NO. 14502

Revision No. 00

Prepared by: *[Signature]*

Date Prepared: 12/23/94

Approved by:

[Signature]

Quality Assurance Director

Date: 12/29/94

[Signature]

Manufacturing Operations Director

Date: 12/27/94

[Signature]

Regulatory Affairs Director

Date: 12/28/94

[Signature]

Quality Control Director

Date: 12/27/94

[Signature]

VP Operations

Date: 12-27-94

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION SUMMARY

PRODUCT	DIGOXIN TABLETS, 0.125 mg	BATCH	4318A
			4320A
			4322A

The following comments apply to the three 1,600,000 tablet validation batches produced in this series.

This report includes data through Compression, which is the finished dosage form.

The process used to produce this batch follows exactly that shown in the normal batch record. Copies of the actual batch records are available in the file.

The data supporting the validation of the analytical methods used may be found in the Analytical Method Validation Report issued for this product.

A copy of the protocol to be followed for this project is included.

Evaluation of the data includes calculation of the Process Capability Index, Cp, when appropriate. Cp is a measure of the ability of a process to produce material that is all within the specification range. It verifies that the entire distribution curve for the data collected falls within the allowable limits. The following equation is used.

$$Cp = \frac{(\text{Upper Limit} - \text{Lower Limit})}{6 \times \text{St. Dev.}}$$

Any value equal to or greater than 1 is acceptable.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

CONCLUSIONS AND OBSERVATIONS

All samples met the established acceptance criteria.

Based on these three batches, the process is considered validated and is acceptable for use.

The data verifies the initial acceptance criteria for all parameters. At this point no revision to any of these ranges will be made.

The final blends showed adequate uniformity for all batches. The resulting Cp value is 2.9, which is more than acceptable.

Content uniformity results are all within the acceptance criteria, and are essentially comparable to the blend results.

Results for both the final blends and content uniformity center around the label amount.

All Dissolution samples for the three batches met the USP requirements. The values for the three batches are comparable, however there is some variability within the individual batches.

The data for each protocol step follows a summary of that step, in the order in which it appears in the protocol.

Amide Pharmaceutical, Inc.

Process Validation

DIGOXIN TABLETS, 0.125 mg

Process Validation Summary

Batch Size - 1,600,000 Tablets

Test	Initial Limits	Batch	4318A	4320A	4322A	Combined	Final Limits
Final Blend Assay (%)	85.0 - 115.0 %Th. (Ind.)	Average	98.5	98.8	98.3	98.5	85.0 - 115.0 %Th. (Ind.)
		Std Dev	1.0	1.5	1.0	1.1	
		Cp				2.9	
Compression Weight (g)	0.097 - 0.113 g	Average	0.105	0.105	0.105	0.105	0.097 - 0.113 g
		Std Dev	0.002	0.002	0.002	0.002	
		Cp				1.5	
Compression Hardness (KP)	1.0 - 6.0 kp	Average	4.5	4.5	4.6	4.5	1.0 - 6.0 kp
		Std Dev	0.4	0.4	0.4	0.4	
		Cp				2.2	
Compression Thickness (mm)	2.0 - 3.0 mm	Average	2.63	2.62	2.62	2.62	2.0 - 3.0 mm
		Std Dev	0.03	0.03	0.03	0.03	
		Cp				5.7	
Compression Friability (%)	NMT: 1.0 %	Average	0.09	0.08	0.08	0.08	NMT: 1.0 %
		Std Dev	0.03	0.03	0.03	0.03	
Compression Disintegration (min)	N/A	Average	3.2	3.3	3.3	3.3	N/A
		Std Dev	0.4	0.5	0.5	0.5	
Compression Content Uniformity (%)	85.0 - 115.0 % RSD NMT: 6.0 %	Average	101.3	100.4	101.3	101.0	85.0 - 115.0 % RSD NMT: 6.0 %
		Std Dev	1.1	1.7	1.7	1.6	
		Cp				3.2	
Compression Dissolution (%) 15 min.	NMT: 90% (ind.)	Average	83.0	85.0	81.4	83.1	NMT: 90% (ind.)
		Std Dev	2.2	2.1	2.5	2.7	
Compression Dissolution (%) 60 min.	NLT: 80% (avg)	Average	97.2	99.7	97.2	98.0	NLT: 80% (avg)
		Std Dev	2.3	3.2	3.1	3.1	

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

PROTOCOL STEP - RAW MATERIALS

The raw materials used will be tested, as stated in the protocol, in accordance with approved specifications and methods. In addition, bulk density, tamped density and particle size distribution will be included.

ACCEPTANCE CRITERIA

Parameters normally evaluated will be compared to the current specifications. The density and particle size data will be gathered and used to formulate guidelines when sufficient data is accumulated.

RESULTS - See attached data summary sheets.

CONCLUSIONS AND COMMENTS

All data is acceptable.

Any differences noted do not appear to have any effect on finished product quality.

Particle size determinations were run on two different pieces of equipment. One is a "Ro-Tap" type unit and the other a Micron Air Jet Sieve. For samples run on the "Ro-Tap" the coarser mesh screen is listed first.

It should be noted that particle size and density evaluation was not done for the Yellow Lake Blend. Since this material is present in such a small amount any differences in either of these parameters will have no significant effect on the final blend.

The particle size distribution for Digoxin P.O. No. 2629-1 was run on the "Ro-Tap" type shaker. That for P.O. No. 3929 was run on the Micron Air Jet Sieve. The results obtained on the two units differed significantly. Due to the fact the the two units employ different technologies no comparison will be made. It should be noted that no effect on content uniformity or dissolution was observed.

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg****Raw Material Usage Chart**

Item #	Item Name	Batch # 4318A P.O. #	Batch # 4320A P.O. #	Batch # 4322A P.O. #
3115	Corn Starch, NF	4025	4025	4025
0111	Digoxin, USP	2629-1	2629-1 & 3929	3929
3044	D&C Yellow #10 Aluminum Lake 15-20%	3844	3844	3844
3000	Croscarmellose Sodium, NF	4026	4026	4026
3051	Lactose Hydrous Impalpable, NF	4028-1	4028-1	4028-1
3088	Starch Pregelatinized, NF	4027	4027	4027
3059	Microcystalline Cellulose, NF	4023	4023	4023
3050	Lactose Anhydrous, NF	4015	4015	4015
3089	Stearic Acid, NF	3910	3910	3910
3081	Silicon Dioxide, NF	3696	3696	3696

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Corn Starch, NF (3115)

P.O. #	4025
Test Type	Initial
Manufacturer	
Manufacturer Lot #	HD-6628

PARAMETERS	SPECIFICATIONS	
DESCRIPTION	Passes Test	Passes
IDENTIFICATION A	Positive	Passes
IDENTIFICATION B	Positive	Passes
MICROBIAL LIMITS	Passes Test	Passes
PH	4.5 - 7.0	5.7
LOSS ON DRYING	NMT 14.0%	2.1%
RESIDUE ON IGNITION	NMT 0.5%	0.1%
IRON	NMT 0.002%	< 0.002%
OXIDIZING SUBSTANCES	Passes Test	Passes
SULFER DIOXIDE	Passes Test	Passes
BULK DENSITY		0.52 g/mL
TAP DENSITY		0.72 g/mL
PARTICULAR SIZE (US 325)	% Retained	3.9%
PARTICULAR SIZE (US 200)	% Retained	2.6%
PARTICULAR SIZE (US 100)	% Retained	NIL

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Digoxin USP (0111)

P.O. #	2629-1	3929
Test Type	Initial	Initial
Manufacturer		
Manufacturer Lot #	240180	240254

PARAMETERS	SPECIFICATIONS	RESULTS	RESULTS
DESCRIPTION	Passes Test	Passes	Passes
IDENTIFICATION A	Positive	Passes	Passes
IDENTIFICATION B	Positive	Passes	Passes
IDENTIFICATION C	Positive	Passes	Passes
LOSS ON DRYING	NMT 1.0%	0.6%	0.7%
RESIDUE ON IGNITION	NMT 0.5%	0.1%	0.1%
RELATED GLYCOSIDES	NMT 3%	< 3%	< 3%
ASSAY	95.0 - 101.0%	98.6%	98.6%
BULK DENSITY		0.24 g/ml	0.23 g/ml
TAP DENSITY		0.37 g/ml	0.36 g/ml
PARTICLE SIZE (US 200)	% Retained	95.6%	N11
PARTICLE SIZE (US 325)	% Retained	4.0%	6.1%

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - D&C Yellow #10 Aluminum Lake 15-20% (3044)

P.O. #	3844
Test Type	Initial
Manufacturer	
Manufacturer Lot #	Aa-7934

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION	Positive	Passes
Loss on Drying	N/A	15.4%

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Croscarmellose Sodium, NF (3000)

P.O. #	4026
Test Type	Initial
Manufacturer	
Manufacturer Lot #	T434N

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION A	Positive	Passes
IDENTIFICATION B	Positive	Passes
IDENTIFICATION C	Positive	Passes
PH	5.0 - 7.0	6.5
LOSS ON DRYING	NMT 10.0%	2.5%
HEAVY METALS	NMT 0.001%	< 0.001%
SODIUM CHLORIDE & SODIUM STARCH GLYCOLATE	NMT 0.5%	0.21%
DEGREE OF SUBSTITUTION	0.60 to 0.85	0.69
CONTENT OF WATER SOLUBLE MATERIAL	1.0% - 10.0%	3.2%
SETTLING VOLUME	10.0 mL - 30.0 mL	22 mL
MICROBIAL TEST		Passes
BULK DENSITY		0.50 g/mL
TAP DENSITY		0.72 g/mL
PARTICLE SIZE (US 325)	% Retained	5.7%
PARTICLE SIZE (US 200)	% Retained	0.9%

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Lactose Hydrous Impalpable NF (3051)

P.O. #	4028-1
Test Type	Initial
Manufacturer	
Manufacturer Lot #	034/435

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION A	Positive	Passes
IDENTIFICATION B	Positive	Passes
CLARITY AND COLOR OF SOLUTION	Passes Test	Passes
LOSS ON DRYING	NMT 1.0%	0.3%
SPECIFIC ROTATION	+54.8° to +55.5°	+55.3°
MICROBIAL LIMITS	Passes Test	Passes
WATER	Hydrous: NMT 5.5%	5.1%
RESIDUE ON IGNITION	NMT 0.1%	0.03%
HEAVY METALS	NMT 5 ppm	< 5 ppm
ACIDITY/ALKALINITY	Passes Test	Passes
PROTEIN/LIGHT ABSORBING IMPUR.	Passes Test	Passes
ORGANIC VOLATILE IMPURITIES	Passes Test	Passes
BULK DENSITY		0.58 g/mL
TAP DENSITY		0.87 g/mL
PARTICAL SIZE (US 200)	% Retained	83.7%
PARTICAL SIZE (US 325)	% Retained	11.3

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Starch Pregelatinized NF (3088)

P.O. #	4027
Test Type	Initial
Manufacturer	
Manufacturer Lot #	403107

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION	Positive	Passes
PH	4.5 - 7.0	5.9
IRON	NMT 0.002%	<0.002 %
OXIDIZING SUBSTANCES	Passes Test	Passes
SULFUR DIOXIDE	NMT: 0.008%	Passes
MICROBIAL LIMITS	Passes Test	Passes
LOSS ON DRYING	NMT 14.0%	8.8%
RESIDUE ON IGNITION	NMT 0.5%	0.2%
BULK DENSITY		0.66 g/mL
TAP DENSITY		0.84 g/mL
PARTICAL SIZE (US 100)	% Accumulation	2.7%
PARTICAL SIZE (US 200)	% Accumulation	26.6%
PARTICAL SIZE (US 325)	% Accumulation	51.5%

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Microcrystalline Cellulose, NF (3059)

P.O. #	4023
Test Type	Initial
Manufacturer	
Manufacturer Lot #	4583

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION	Positive	Passes
PH	5.5 to 7.0	6.1
LOSS ON DRYING	NMT 5.0%	2.5%
RESIDUE ON IGNITION	NMT 0.05%	0.02%
WATER SOLUBLE SUBSTANCES	NMT 0.16%	0.10%
HEAVY METALS	NMT 0.001%	<0.001%
STARCH	Passes Test	Passes
ASSAY	97.0% - 102.0%	99.7%
BULK DENSITY		0.34 g/m
TAP DENSITY		0.43 g/m
PARTICAL SIZE (US 325)	% Retained	44.7%
PARTICAL SIZE (US 200)	% Retained	20.6%
PARTICAL SIZE (US 100)	% Retained	NIL

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Lactose Anhydrous, NF (DT) (3050)

P.O. #	4015
Test Type	Initial
Manufacturer	
Manufacturer Lot #	MRP54536

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION A	Positive	Passes
IDENTIFICATION B	Positive	Passes
CLARITY AND COLOR OF SOLUTION	Passes Test	Passes
LOSS ON DRYING	NMT 0.5%	0.2%
SPECIFIC ROTATION	Between +54.8° and +55.5°	+55.2°
MICROBIAL LIMITS	NMT 100 per gm	Passes
WATER	NMT 1.0%	0.4%
RESIDUE ON IGNITION	NMT 0.1%	0.04%
HEAVY METALS	NMT 5 ppm	< 5 ppm
ACIDITY/ALKALINITY	Passes Test	Passes
PROTEIN AND LIGHT ABSORBING IMPURITIES	NMT 0.25	Passes
ORGANIC VOLATILE IMPURITIES	Passes Test	Passes
BULK DENSITY		0.57 g/m
TAP DENSITY		0.81 g/m
PARTIAL SIZE (US 100)	% Accumulation	13.1%
PARTIAL SIZE (US 200)	% Accumulation	28.6%
PARTIAL SIZE (US 325)	% Accumulation	40.5%

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Stearic Acid, NF (3089)

P.O. #	3910
Test Type	Initial
Manufacturer	
Manufacturer Lot #	440069

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
CONGEALING TEMPERATURE	NLT 54°	55°
RESIDUE ON IGNITION	NMT 0.1%	0.01
HEAVY METALS	NMT 0.001%	<0.001
MINERAL ACID	Passes Test	Passes
NEUTRAL FAT OR PARAFIN	Passes Test	Passes
IODINE VALUE	NMT 4	0.10
ASSAY A	NLT 40.0%	43.4%
ASSAY B	NLT 90.0%	96.4%
ORGANIC VOLATILE IMPURITIES	Passes Test	Passes
BULK DENSITY		0.38 g/ml
TAP DENSITY		0.49 g/ml
PARTICAL SIZE (US 325)	% Retained	54.0%
PARTICAL SIZE (US 200)	% Retained	6.4%

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Raw Material Comparison - Silicon Dioxide, NF (3081)

P.O. #	3696
Test Type	Initial
Manufacturer	
Manufacturer Lot #	4-90

PARAMETERS	SPECIFICATIONS	RESULTS
DESCRIPTION	Passes Test	Passes
IDENTIFICATION	Positive	Passes
PH	4 - 8	6.7
LOSS ON DRYING	NMT 5.0%	4.0%
CHLORIDE	NMT 0.1%	<0.1%
SULFATE	NMT 0.5%	<0.5%
ARSENIC	NMT 3 ppm	<3 ppm
HEAVY METAL	NMT 0.003%	<0.003%
ASSAY	NLT 99.0%	99.6%
BULK DENSITY		0.10 g/ml
TAP DENSITY		0.13 g/ml
PARTICLE SIZE (US 325)	% Retained	Nil

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14802 - 00

PROTOCOL STEP - TEMPERATURE/HUMIDITY READINGS

Temperature and humidity readings will be taken in the production area. These three batches ran in production between 11/8/94 and 11/18/94.

RESULTS - See attached data summary sheets.

CONCLUSIONS AND COMMENTS

The temperature ranged from 58 - 65° F, and the relative humidity from 43 - 58%. It should be noted that this is the first production in the new production rooms and that inadvertently some readings were not taken. The data collected indicates that acceptable product can be made under these conditions.

AMIDE PHARMACEUTICAL, INC.

TEMPERATURE/HUMIDITY READINGS

PERIOD COVERING DIGOXIN TABLETS, 0.125 mg

BATCHES 4318A, 4320A, AND 4322A

LOCATION	DATE	TEMP. (Deg. F)	RH (%)
Near Pr. Rm. #117	11-Nov-94	58	43
Near Pr. Rm. #117	18-Nov-94	65	58

**AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION**

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

STEP - BLEND UNIFORMITY

Utilizing a sampling thief, sample each of the blenders from the positions shown on the attached data summary. Separately analyze, and report, each one for active ingredient content.

The speed of each blender will be monitored both empty and at each stage of blending.

ACCEPTANCE CRITERIA

Final Blend - 85.0 - 115.0 % Th. (Individual)

RESULTS - See the attached data summary.

CONCLUSIONS AND COMMENTS

The final blends for the three batches met all acceptance criteria and appear to be uniformly blended.

The bulk and tamped density results are comparable for all three batches.

The speed for both blenders was observed to be constant throughout production of the three batches. The same speed was obtained both empty and under load. The supporting documentation is attached.

3 Cu. Ft. (32) - 22 rpm
10 Cu. Ft. (35) - 16 rpm

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

FINAL BLEND - Assay (% Label)

	Batch #	Batch #	Batch #	Batch #
	4318A	4320A	4322A	
Left Column - Top Left	98.1	96.4	97.6	
Left Column - Top Center	97.9	97.8	98.1	
Left Column - Top Right	98.6	97.2	98.6	
Right Column - Top Left	97.9	99.6	98.0	
Right Column - Top Center	98.3	98.0	97.5	
Right Column - Top Right	98.3	98.4	98.3	
Middle Left	96.8	99.2	99.4	
Middle Center	100.1	100.4	100.1	
Middle Right	100.1	100.8	98.1	
Bottom Left	98.0	98.0	96.7	
Bottom Right	99.0	100.7	99.1	
Average	98.5	98.8	98.3	
St Dev.	1.0	1.5	1.0	
RSD	1.0	1.5	1.0	

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

FINAL BLEND - Density/Particle Size - Batch # 4318A

Density (g/ml)

	Top Center	Top Left	Top Right
Bulk	0.61	0.61	0.61
Tap	0.89	0.89	0.90

Particle Size (% Retained)

Mesh Size	Top Center	Top Left	Top Right
325	54.5	53.3	54.3
200	34.8	34.5	34.8
100	14.6	14.9	15.1
60	4.4	4.5	4.2
40	Nil	Nil	Nil

FINAL BLEND - Density/Particle Size - Batch # 4320A

Density (g/ml)

	Top Center	Top Left	Top Right
Bulk	0.62	0.61	0.61
Tap	0.91	0.90	0.90

Particle Size (% Retained)

Mesh Size	Top Center	Top Left	Top Right
325	53.7	53.7	53.6
200	34.3	34.5	34.1
100	14.9	15.2	15.1
60	4.2	4.5	4.7
40	Nil	Nil	Nil

FINAL BLEND - Density/Particle Size - Batch # 4322A

Density (g/ml)

	Top Center	Top Left	Top Right
Bulk	0.61	0.61	0.61
Tap	0.90	0.90	0.90

Particle Size (% Retained)

Mesh Size	Top Center	Top Left	Top Right
325	53.1	53.4	53.0
200	34.1	34.6	34.2
100	15.3	15.3	15.1
60	4.2	4.1	4.4
40	Nil	Nil	Nil

BLENDER 1: 35

PD2-046

PRODUCT NAME (1): Digoxin Tablets 0.125mg (145)

BATCH #: 4320A MFR #: 14502 REV #: 00 DATE: 11/10/94

BLENDER #: 35

[illegible]

ACTAV 001867021

PRODUCT NAME (1): Digoxin Tablets 0.125mg (145)

BATCH : 4322A

HPR : 14502

REV 1: 00

DATE: 11/11/94

BLENDER : 32

[illegible]

PO2-044

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

PROTOCOL STEP - COMPRESSION

Samples were taken from each side of the press each 30 minutes and were evaluated for the following parameters.

Weight (n = 10)
Thickness (n = 5)
Hardness (n = 5)

These samples will be arranged chronologically and the batch divided into thirds. Front and rear will be analyzed separately as follows.

Friability	10 g - 1 run
Dissolution	N = 12 (6 front & 6 rear)
Disintegration	N = 6

Content uniformity is to be run across the entire batch. One tablet from each sample taken is to be run from the front, and one from the rear. A minimum of 30 is required from each side.

During compression a minimum quantity of tablets will be run at speeds higher and lower than normal. The actual speeds will be selected during production. These tablets will be evaluated for weight and hardness.

During compression minimum quantities of tablets will be run at hardness of 0.5 - 2 KP and greater than 6 KP. An attempt will also be made to run some tablets at the highest possible hardness that can be obtained without capping. These tablets will be evaluated for Dissolution and Friability.

ACCEPTANCE CRITERIA

Weight: 0.097 - 0.113 g
Hardness: 1.0 - 6.0 KP
Thickness: 2.0 - 3.0 mm
Friability: NMT 1.0 %
Dissolution: Meets USP Requirement
Disintegration: N/A (for characterization only)
Content Uniformity: 85.0 - 115.0 % TH, (RSD NMT 6.0 %)
Assay: 90.0 - 105.0 % Label

RESULTS - See attached data summary sheets.

**AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION**

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

CONCLUSIONS AND COMMENTS

The samples met all acceptance criteria.

The values for weight, hardness, and thickness for the three batches were comparable to each other and showed no unusual shifts or trends. The overall averages for weight, hardness and thickness are very close to the midpoints of the preset ranges. Therefore, no revisions to these limits are indicated by the validation data. Results are attached in both tabular and graphical form.

Content Uniformity was within limits for all samples tested, with no significant trends being observed. All values were within 93 - 105 % Label. The values obtained were observed to agree favorably with the blend assays. It should be noted that the averages for the blend assays, and the content uniformity results are essentially the label amount.

All Dissolution samples for the three batches met the USP requirements. This statement is true for both USP XXII (60 Min.) and XXIII (15 & 60 Min.). The values for the three batches were comparable.

Friability values were all well within the acceptance criteria, and comparable for the three batches.

Disintegration results were comparable with no unusual shifts or trends. Note that this test was run for characterization only, and therefore no acceptance criteria have been, or will be, established.

Acceptable tablets were produced at the low press speed for all three batches, and at high speed for batches 4318A & 4320A. Unacceptable tablets (weight variability) were produced at high speed for batch 4322A. The normal, high, and low operating speeds for each batch are as follows. Based on the data obtained here, the press may be safely run as slow as 14 rpm. No upper limit can be set at this time.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg MPR NO. 14502 - 00

BATCH	NORMAL	HIGH	LOW
4318A	21 rpm	26 rpm	14 rpm
4320A	21 rpm	26 rpm	14 rpm
4322A	21 rpm	26 rpm	14 rpm

The high and low hardness validation produced acceptable tablets at both ends of the range. Tablets with hardness above the upper limit could not be produced. Therefore the guideline will remain at 1.0 - 6.0 KP. The values for friability are listed below. Those for dissolution are attached.

FRIABILITY (%)

BATCH	4318A	4320A	4322A
LOW KP FRONT	0.2	0.2	0.04
REAR	0.1	0.2	0.2
HIGH KP FRONT	0.03	0.1	0.04
REAR	0.04	0.04	0.1

The results for the overall composites are attached. These are also all within the acceptance criteria, and are essentially comparable to those obtained for the individual samples.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 4318A

Compression - Weight (g) - Front

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/11/94	1:50 PM	0.105	0.104	0.105	0.106	0.106	0.106	0.107	0.105	0.102	0.104	0.105	0.001	1.3
11/11/94	2:45 PM	0.104	0.105	0.105	0.105	0.104	0.107	0.104	0.103	0.105	0.103	0.105	0.001	1.1
11/11/94	3:20 PM	0.106	0.106	0.108	0.105	0.107	0.106	0.106	0.105	0.108	0.107	0.106	0.001	1.0
11/11/94	4:00 PM	0.105	0.106	0.109	0.105	0.103	0.106	0.104	0.106	0.104	0.106	0.105	0.001	1.3
11/11/94	4:30 PM	0.108	0.104	0.105	0.107	0.108	0.107	0.105	0.106	0.105	0.106	0.106	0.001	1.3
11/12/94	7:25 AM	0.108	0.107	0.107	0.106	0.107	0.107	0.108	0.106	0.106	0.107	0.107	0.001	0.7
11/12/94	7:55 AM	0.106	0.109	0.108	0.106	0.108	0.106	0.110	0.107	0.108	0.108	0.108	0.001	1.3
11/12/94	8:25 AM	0.105	0.107	0.104	0.106	0.105	0.112	0.106	0.107	0.105	0.105	0.106	0.002	2.1
11/12/94	8:55 AM	0.109	0.107	0.104	0.105	0.105	0.105	0.103	0.107	0.107	0.105	0.106	0.002	1.7
11/12/94	9:25 AM	0.105	0.106	0.106	0.104	0.106	0.106	0.107	0.105	0.107	0.106	0.106	0.001	0.9
11/12/94	9:55 AM	0.106	0.109	0.106	0.108	0.104	0.107	0.106	0.106	0.104	0.107	0.106	0.002	1.5
11/12/94	10:25 AM	0.103	0.104	0.108	0.107	0.107	0.105	0.108	0.105	0.108	0.106	0.106	0.002	1.7
11/12/94	11:50 AM	0.105	0.108	0.106	0.103	0.106	0.107	0.105	0.103	0.104	0.106	0.105	0.002	1.6
11/12/94	12:20 PM	0.098	0.106	0.105	0.104	0.105	0.105	0.108	0.105	0.104	0.107	0.105	0.003	2.5
11/12/94	12:50 PM	0.105	0.106	0.105	0.107	0.104	0.106	0.106	0.109	0.107	0.105	0.106	0.001	1.3
11/12/94	1:20 PM	0.106	0.104	0.105	0.104	0.106	0.103	0.105	0.104	0.104	0.105	0.105	0.001	0.9
11/12/94	1:50 PM	0.103	0.104	0.103	0.106	0.104	0.104	0.104	0.107	0.105	0.105	0.105	0.001	1.2
11/12/94	2:20 PM	0.105	0.103	0.104	0.105	0.105	0.105	0.105	0.104	0.105	0.106	0.105	0.001	0.8
11/14/94	8:20 AM	0.106	0.104	0.106	0.104	0.105	0.105	0.104	0.109	0.105	0.103	0.105	0.002	1.6
11/14/94	8:45 AM	0.104	0.105	0.103	0.106	0.106	0.106	0.106	0.107	0.103	0.104	0.105	0.001	1.3
11/14/94	9:15 AM	0.106	0.106	0.107	0.107	0.105	0.105	0.105	0.106	0.106	0.106	0.106	0.001	0.7
11/14/94	9:45 AM	0.105	0.106	0.106	0.104	0.106	0.105	0.104	0.104	0.105	0.106	0.105	0.001	0.8
11/14/94	10:15 AM	0.104	0.105	0.106	0.104	0.106	0.104	0.105	0.103	0.105	0.106	0.105	0.001	1.0
11/14/94	10:45 AM	0.106	0.106	0.106	0.103	0.105	0.107	0.103	0.106	0.107	0.104	0.105	0.001	1.4
11/14/94	1:25 PM	0.103	0.105	0.104	0.105	0.102	0.107	0.107	0.106	0.104	0.104	0.105	0.002	1.6
11/14/94	1:50 PM	0.106	0.103	0.105	0.105	0.103	0.104	0.107	0.104	0.106	0.104	0.105	0.001	1.3
11/14/94	2:45 PM	0.105	0.105	0.106	0.106	0.105	0.106	0.104	0.105	0.106	0.102	0.105	0.001	1.2

Compression - Weight (g) - Rear

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/11/94	1:50 PM	0.106	0.102	0.104	0.104	0.100	0.107	0.103	0.104	0.106	0.103	0.104	0.002	2.0
11/11/94	2:45 PM	0.105	0.107	0.104	0.105	0.106	0.102	0.105	0.107	0.105	0.104	0.105	0.001	1.4
11/11/94	3:20 PM	0.107	0.102	0.104	0.108	0.106	0.105	0.103	0.105	0.108	0.103	0.105	0.002	2.0
11/11/94	4:00 PM	0.103	0.108	0.109	0.105	0.106	0.103	0.104	0.103	0.107	0.107	0.106	0.002	2.1
11/11/94	4:30 PM	0.106	0.101	0.106	0.108	0.104	0.107	0.106	0.103	0.105	0.100	0.105	0.003	2.5
11/12/94	7:25 AM	0.102	0.105	0.106	0.109	0.107	0.107	0.104	0.105	0.109	0.107	0.106	0.002	1.9
11/12/94	7:55 AM	0.109	0.104	0.105	0.108	0.107	0.109	0.108	0.107	0.103	0.101	0.106	0.003	2.6
11/12/94	8:25 AM	0.106	0.108	0.103	0.104	0.107	0.107	0.109	0.103	0.107	0.109	0.106	0.002	2.1
11/12/94	8:55 AM	0.103	0.104	0.107	0.108	0.109	0.107	0.107	0.109	0.103	0.105	0.106	0.002	2.2
11/12/94	9:25 AM	0.106	0.103	0.102	0.104	0.104	0.102	0.104	0.106	0.100	0.105	0.104	0.002	1.8
11/12/94	9:55 AM	0.106	0.103	0.107	0.107	0.108	0.104	0.104	0.107	0.109	0.104	0.106	0.002	1.9
11/12/94	10:25 AM	0.104	0.105	0.102	0.104	0.106	0.105	0.107	0.104	0.106	0.104	0.105	0.001	1.4
11/12/94	11:50 AM	0.107	0.107	0.107	0.107	0.100	0.108	0.105	0.102	0.107	0.106	0.106	0.003	2.5
11/12/94	12:20 PM	0.107	0.105	0.108	0.104	0.107	0.103	0.102	0.104	0.107	0.107	0.105	0.002	2.0
11/12/94	12:50 PM	0.106	0.105	0.107	0.104	0.108	0.106	0.110	0.106	0.105	0.105	0.106	0.002	1.6
11/12/94	1:20 PM	0.106	0.105	0.105	0.105	0.104	0.104	0.107	0.106	0.107	0.110	0.106	0.002	1.7
11/12/94	1:50 PM	0.107	0.107	0.107	0.106	0.107	0.105	0.105	0.108	0.107	0.105	0.106	0.001	1.0
11/12/94	2:20 PM	0.106	0.107	0.105	0.107	0.104	0.107	0.106	0.109	0.106	0.107	0.106	0.001	1.3
11/14/94	8:20 AM	0.104	0.105	0.103	0.108	0.105	0.106	0.104	0.109	0.107	0.104	0.105	0.002	1.7
11/14/94	8:45 AM	0.101	0.107	0.104	0.104	0.106	0.103	0.104	0.105	0.107	0.105	0.105	0.002	1.8
11/14/94	9:15 AM	0.106	0.104	0.106	0.104	0.102	0.104	0.105	0.107	0.105	0.104	0.105	0.001	1.4
11/14/94	9:45 AM	0.107	0.106	0.104	0.104	0.103	0.102	0.106	0.103	0.106	0.106	0.105	0.002	1.6
11/14/94	10:15 AM	0.103	0.105	0.103	0.107	0.105	0.106	0.104	0.104	0.105	0.106	0.105	0.001	1.3
11/14/94	10:45 AM	0.105	0.101	0.105	0.108	0.103	0.102	0.102	0.106	0.104	0.106	0.104	0.002	2.1
11/14/94	1:25 PM	0.107	0.103	0.103	0.106	0.105	0.106	0.103	0.106	0.105	0.109	0.105	0.002	1.8
11/14/94	1:50 PM	0.103	0.104	0.102	0.104	0.110	0.105	0.107	0.105	0.106	0.104	0.105	0.002	2.2
11/14/94	2:45 PM	0.104	0.104	0.103	0.106	0.106	0.106	0.107	0.103	0.103	0.107	0.105	0.002	1.6

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 4320A

Compression - Weight (g) - Front

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/14/94	5:15 PM	0.104	0.105	0.106	0.105	0.105	0.104	0.103	0.107	0.104	0.105	0.105	0.001	1.1
11/14/94	5:45 PM	0.106	0.106	0.104	0.103	0.105	0.105	0.105	0.102	0.103	0.104	0.104	0.001	1.3
11/14/94	6:15 PM	0.107	0.105	0.104	0.104	0.104	0.104	0.108	0.106	0.106	0.104	0.105	0.001	1.4
11/14/94	6:45 PM	0.102	0.106	0.103	0.106	0.104	0.106	0.107	0.103	0.105	0.105	0.105	0.002	1.6
11/14/94	7:15 PM	0.106	0.105	0.104	0.104	0.102	0.106	0.103	0.103	0.105	0.103	0.104	0.001	1.3
11/14/94	7:45 PM	0.107	0.104	0.105	0.104	0.104	0.106	0.106	0.105	0.103	0.106	0.105	0.001	1.2
11/14/94	8:15 PM	0.106	0.105	0.105	0.107	0.107	0.105	0.105	0.107	0.108	0.109	0.106	0.001	1.3
11/14/94	8:45 PM	0.104	0.106	0.108	0.107	0.109	0.106	0.106	0.105	0.107	0.105	0.106	0.001	1.4
11/15/94	8:00 AM	0.108	0.105	0.109	0.104	0.106	0.107	0.108	0.107	0.107	0.106	0.107	0.001	1.4
11/15/94	8:30 AM	0.105	0.106	0.106	0.104	0.104	0.107	0.107	0.104	0.106	0.104	0.105	0.001	1.2
11/15/94	9:00 AM	0.107	0.104	0.106	0.103	0.105	0.106	0.104	0.105	0.104	0.107	0.105	0.001	1.3
11/15/94	9:30 AM	0.107	0.107	0.106	0.106	0.106	0.106	0.107	0.105	0.105	0.107	0.106	0.001	0.7
11/15/94	10:00 AM	0.104	0.104	0.101	0.106	0.106	0.103	0.103	0.103	0.104	0.103	0.104	0.001	1.4
11/15/94	10:30 AM	0.104	0.105	0.106	0.105	0.104	0.106	0.104	0.106	0.105	0.105	0.105	0.001	0.8
11/15/94	11:35 AM	0.107	0.106	0.104	0.107	0.106	0.105	0.106	0.105	0.107	0.106	0.106	0.001	0.9
11/15/94	12:05 PM	0.104	0.105	0.108	0.103	0.107	0.106	0.105	0.106	0.105	0.106	0.106	0.001	1.4
11/15/94	12:35 PM	0.107	0.106	0.105	0.107	0.107	0.105	0.106	0.104	0.104	0.105	0.106	0.001	1.1
11/15/94	1:05 PM	0.106	0.104	0.107	0.105	0.107	0.106	0.105	0.104	0.105	0.106	0.106	0.001	1.0
11/15/94	1:35 PM	0.105	0.106	0.104	0.106	0.104	0.108	0.107	0.106	0.105	0.105	0.106	0.001	1.2
11/15/94	4:30 PM	0.105	0.108	0.107	0.108	0.106	0.104	0.105	0.107	0.107	0.104	0.106	0.002	1.4
11/15/94	5:00 PM	0.105	0.105	0.106	0.107	0.108	0.105	0.105	0.107	0.105	0.105	0.106	0.001	1.1
11/15/94	5:30 PM	0.107	0.105	0.104	0.106	0.104	0.105	0.107	0.104	0.106	0.106	0.105	0.001	1.1
11/15/94	6:10 PM	0.106	0.104	0.105	0.105	0.107	0.102	0.107	0.106	0.104	0.108	0.105	0.002	1.7
11/15/94	6:40 PM	0.103	0.104	0.106	0.104	0.106	0.105	0.102	0.106	0.106	0.105	0.105	0.001	1.4
11/15/94	7:10 PM	0.103	0.105	0.103	0.106	0.103	0.106	0.105	0.105	0.102	0.106	0.104	0.002	1.4
11/15/94	7:40 PM	0.104	0.105	0.105	0.105	0.104	0.103	0.107	0.105	0.105	0.107	0.105	0.001	1.2
11/15/94	8:10 PM	0.104	0.105	0.104	0.104	0.106	0.105	0.104	0.106	0.104	0.104	0.105	0.001	0.8
11/15/94	8:40 AM	0.106	0.104	0.105	0.103	0.102	0.105	0.104	0.105	0.103	0.103	0.104	0.001	1.2
11/15/94	9:10 AM	0.103	0.106	0.106	0.104	0.104	0.105	0.105	0.103	0.104	0.107	0.105	0.001	1.3

Compression - Weight (g) - Rear

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/14/94	5:15 PM	0.107	0.103	0.102	0.107	0.103	0.108	0.105	0.104	0.105	0.101	0.105	0.002	2.2
11/14/94	5:45 PM	0.104	0.105	0.102	0.105	0.105	0.105	0.101	0.103	0.106	0.105	0.104	0.002	1.5
11/14/94	6:15 PM	0.106	0.102	0.100	0.105	0.101	0.105	0.104	0.106	0.106	0.104	0.104	0.002	2.1
11/14/94	6:45 PM	0.104	0.100	0.101	0.100	0.100	0.102	0.104	0.102	0.102	0.100	0.102	0.002	1.6
11/14/94	7:15 PM	0.104	0.101	0.100	0.102	0.101	0.104	0.104	0.100	0.100	0.101	0.102	0.002	1.7
11/14/94	7:45 PM	0.108	0.102	0.107	0.106	0.107	0.103	0.104	0.104	0.104	0.105	0.105	0.002	1.9
11/14/94	8:15 PM	0.108	0.104	0.107	0.108	0.105	0.104	0.106	0.104	0.108	0.108	0.106	0.002	1.7
11/14/94	8:45 PM	0.108	0.106	0.107	0.104	0.108	0.106	0.106	0.105	0.102	0.106	0.106	0.002	1.7
11/15/94	8:00 AM	0.107	0.105	0.107	0.104	0.107	0.108	0.110	0.108	0.108	0.107	0.107	0.002	1.6
11/15/94	8:30 AM	0.102	0.105	0.102	0.104	0.105	0.104	0.106	0.105	0.103	0.102	0.104	0.001	1.4
11/15/94	9:00 AM	0.106	0.104	0.101	0.106	0.101	0.102	0.107	0.107	0.103	0.103	0.104	0.002	2.3
11/15/94	9:30 AM	0.107	0.105	0.101	0.107	0.104	0.102	0.106	0.103	0.106	0.104	0.105	0.002	2.0
11/15/94	10:00 AM	0.105	0.103	0.105	0.104	0.104	0.105	0.107	0.103	0.105	0.105	0.105	0.001	1.1
11/15/94	10:30 AM	0.103	0.102	0.106	0.105	0.103	0.103	0.106	0.104	0.106	0.109	0.105	0.002	2.0
11/15/94	11:35 AM	0.107	0.108	0.105	0.103	0.103	0.104	0.103	0.102	0.103	0.104	0.104	0.002	1.9
11/15/94	12:05 PM	0.108	0.105	0.104	0.107	0.103	0.107	0.102	0.106	0.106	0.104	0.106	0.002	1.5
11/15/94	12:35 PM	0.107	0.104	0.106	0.103	0.107	0.102	0.106	0.106	0.105	0.106	0.105	0.002	1.6
11/15/94	1:05 PM	0.102	0.105	0.103	0.107	0.101	0.107	0.105	0.103	0.107	0.105	0.105	0.002	2.1
11/15/94	1:35 PM	0.105	0.106	0.106	0.105	0.105	0.106	0.103	0.102	0.102	0.106	0.105	0.002	1.6
11/15/94	4:30 PM	0.106	0.104	0.106	0.105	0.107	0.107	0.102	0.107	0.103	0.104	0.105	0.002	1.7
11/15/94	5:00 PM	0.109	0.105	0.107	0.105	0.106	0.106	0.105	0.107	0.103	0.104	0.105	0.002	1.5
11/15/94	5:30 PM	0.106	0.104	0.104	0.106	0.104	0.105	0.107	0.106	0.106	0.103	0.105	0.001	1.2
11/15/94	6:10 PM	0.104	0.104	0.107	0.104	0.104	0.103	0.103	0.103	0.106	0.102	0.104	0.001	1.4
11/15/94	6:40 PM	0.104	0.105	0.103	0.104	0.102	0.105	0.101	0.103	0.105	0.106	0.104	0.002	1.5
11/15/94	7:10 PM	0.104	0.103	0.107	0.100	0.104	0.102	0.105	0.104	0.105	0.104	0.104	0.002	1.8
11/15/94	7:40 PM	0.106	0.105	0.105	0.106	0.106	0.106	0.104	0.104	0.106	0.106	0.105	0.001	0.8
11/15/94	8:10 PM	0.103	0.103	0.105	0.105	0.105	0.103	0.102	0.106	0.102	0.104	0.104	0.001	1.4
11/15/94	8:40 AM	0.105	0.102	0.106	0.106	0.106	0.104	0.101	0.102	0.103	0.104	0.104	0.002	1.8
11/15/94	9:10 AM	0.101	0.105	0.101	0.106	0.106	0.105	0.102	0.105	0.102	0.103	0.104	0.002	1.9

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

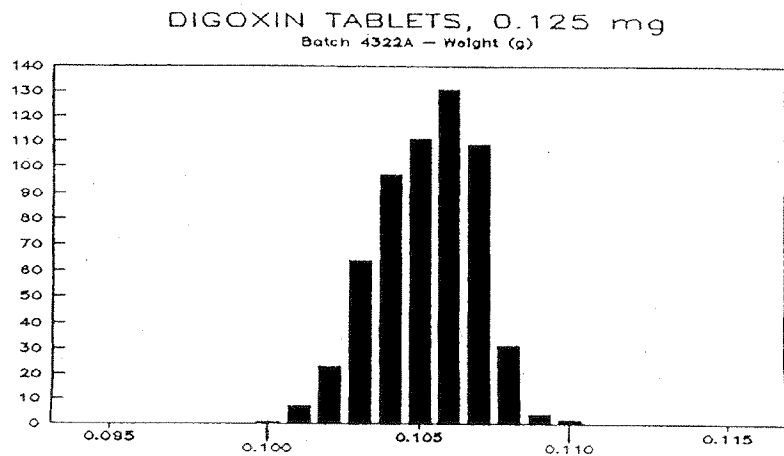
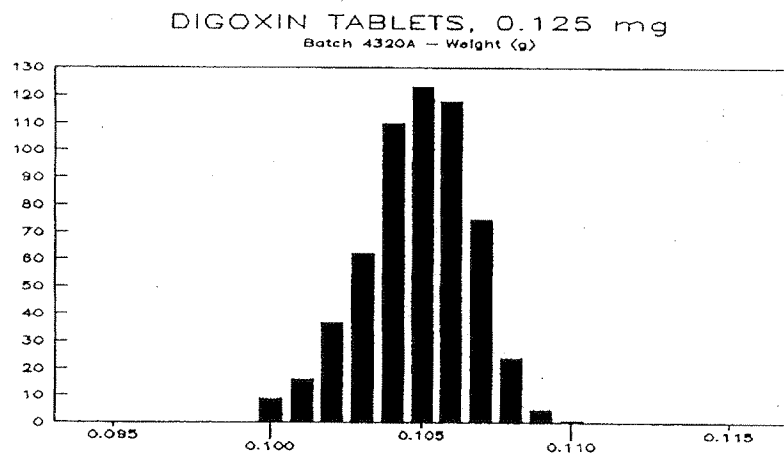
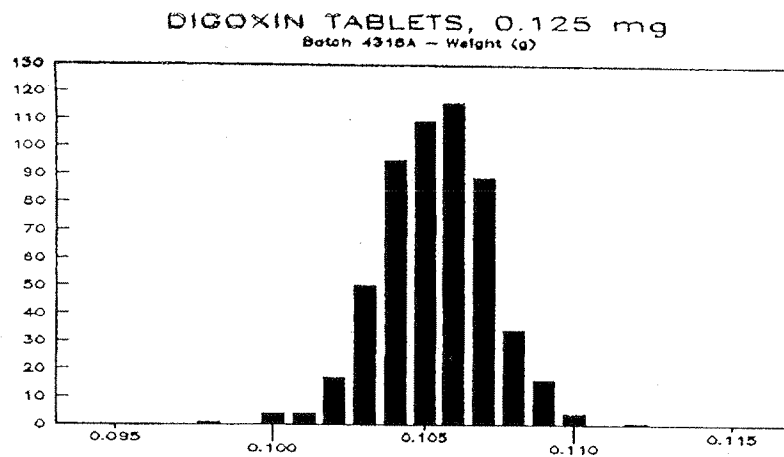
DIGOXIN TABLETS, 0.125 mg - Batch # 4322A

Compression - Weight (g) - Front

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/16/94	12:15 PM	0.104	0.107	0.106	0.106	0.107	0.105	0.105	0.107	0.106	0.107	0.106	0.001	1.0
11/16/94	12:45 PM	0.107	0.105	0.105	0.106	0.106	0.107	0.107	0.107	0.104	0.105	0.106	0.001	1.0
11/16/94	1:15 PM	0.105	0.107	0.106	0.106	0.106	0.106	0.105	0.105	0.107	0.107	0.106	0.001	0.8
11/16/94	1:45 PM	0.103	0.105	0.106	0.104	0.106	0.107	0.106	0.106	0.106	0.105	0.105	0.001	1.1
11/16/94	2:30 PM	0.108	0.106	0.103	0.107	0.105	0.104	0.105	0.106	0.105	0.105	0.105	0.001	1.4
11/16/94	3:00 PM	0.107	0.104	0.104	0.103	0.105	0.105	0.106	0.105	0.106	0.105	0.105	0.001	1.1
11/16/94	3:35 PM	0.106	0.107	0.106	0.104	0.105	0.107	0.104	0.104	0.106	0.106	0.106	0.001	1.1
11/16/94	4:05 PM	0.106	0.104	0.107	0.105	0.105	0.106	0.105	0.105	0.103	0.106	0.105	0.001	1.1
11/16/94	4:35 PM	0.108	0.104	0.106	0.106	0.106	0.105	0.105	0.104	0.105	0.107	0.106	0.001	1.2
11/16/94	5:05 PM	0.105	0.106	0.107	0.105	0.104	0.106	0.104	0.106	0.104	0.105	0.105	0.001	1.0
11/17/94	8:00 AM	0.106	0.106	0.106	0.107	0.107	0.105	0.106	0.106	0.107	0.105	0.106	0.001	0.7
11/17/94	8:30 AM	0.107	0.108	0.106	0.105	0.107	0.104	0.108	0.107	0.108	0.107	0.107	0.001	1.3
11/17/94	9:00 AM	0.103	0.105	0.104	0.105	0.105	0.106	0.107	0.103	0.104	0.107	0.105	0.001	1.4
11/17/94	9:30 AM	0.105	0.105	0.106	0.106	0.105	0.106	0.105	0.106	0.105	0.105	0.105	0.001	0.5
11/17/94	10:00 AM	0.102	0.106	0.107	0.107	0.104	0.105	0.104	0.104	0.104	0.103	0.105	0.002	1.6
11/17/94	10:30 AM	0.103	0.105	0.104	0.104	0.104	0.106	0.100	0.103	0.106	0.105	0.104	0.002	1.7
11/17/94	11:35 AM	0.106	0.104	0.105	0.106	0.106	0.107	0.103	0.106	0.104	0.105	0.105	0.001	1.2
11/17/94	12:05 PM	0.104	0.103	0.103	0.105	0.103	0.103	0.107	0.106	0.103	0.106	0.104	0.002	1.5
11/17/94	12:35 PM	0.105	0.105	0.105	0.106	0.108	0.105	0.105	0.104	0.105	0.107	0.106	0.001	1.1
11/17/94	1:45 PM	0.104	0.103	0.106	0.107	0.106	0.102	0.109	0.106	0.104	0.102	0.105	0.002	2.2
11/17/94	2:35 PM	0.105	0.106	0.105	0.105	0.108	0.105	0.105	0.104	0.104	0.105	0.105	0.001	1.1
11/17/94	3:05 PM	0.105	0.103	0.106	0.106	0.106	0.103	0.104	0.107	0.105	0.105	0.105	0.001	1.3
11/17/94	3:30 PM	0.105	0.106	0.106	0.103	0.106	0.104	0.104	0.104	0.107	0.105	0.105	0.001	1.2
11/17/94	4:00 PM	0.106	0.105	0.105	0.104	0.105	0.105	0.106	0.104	0.106	0.103	0.105	0.001	0.9
11/17/94	4:30 PM	0.107	0.104	0.108	0.107	0.107	0.106	0.104	0.108	0.103	0.106	0.106	0.002	1.7
11/17/94	5:05 PM	0.105	0.105	0.104	0.107	0.106	0.106	0.105	0.104	0.107	0.106	0.106	0.001	1.0
11/17/94	5:35 PM	0.105	0.103	0.103	0.106	0.106	0.105	0.106	0.105	0.105	0.107	0.105	0.001	1.2
11/17/94	6:25 PM	0.104	0.106	0.107	0.107	0.104	0.105	0.105	0.104	0.105	0.105	0.105	0.001	1.1
11/17/94	6:55 PM	0.107	0.104	0.105	0.107	0.104	0.103	0.106	0.106	0.104	0.104	0.105	0.001	1.3

Compression - Weight (g) - Rear

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
11/16/94	12:15 PM	0.107	0.107	0.104	0.107	0.105	0.106	0.108	0.107	0.104	0.106	0.106	0.001	1.3
11/16/94	12:45 PM	0.107	0.108	0.107	0.107	0.105	0.104	0.106	0.105	0.103	0.104	0.106	0.002	1.6
11/16/94	1:15 PM	0.104	0.103	0.104	0.107	0.107	0.104	0.104	0.107	0.106	0.104	0.105	0.002	1.5
11/16/94	1:45 PM	0.104	0.107	0.106	0.104	0.106	0.107	0.104	0.106	0.106	0.104	0.106	0.001	1.2
11/16/94	2:30 PM	0.106	0.107	0.108	0.107	0.103	0.109	0.106	0.102	0.105	0.104	0.106	0.002	2.1
11/16/94	3:00 PM	0.107	0.103	0.110	0.106	0.107	0.105	0.108	0.107	0.108	0.103	0.106	0.002	2.1
11/16/94	3:35 PM	0.107	0.105	0.106	0.108	0.102	0.104	0.102	0.106	0.103	0.108	0.105	0.002	2.2
11/16/94	4:05 PM	0.101	0.106	0.102	0.107	0.102	0.106	0.104	0.108	0.106	0.105	0.105	0.002	2.3
11/16/94	4:35 PM	0.107	0.104	0.102	0.104	0.103	0.106	0.105	0.104	0.103	0.102	0.104	0.002	1.6
11/16/94	5:05 PM	0.103	0.106	0.105	0.104	0.103	0.107	0.103	0.106	0.106	0.105	0.105	0.001	1.4
11/17/94	8:00 AM	0.106	0.108	0.106	0.107	0.108	0.105	0.107	0.110	0.109	0.107	0.107	0.001	1.4
11/17/94	8:30 AM	0.104	0.107	0.103	0.108	0.107	0.109	0.104	0.106	0.108	0.105	0.106	0.002	1.9
11/17/94	9:00 AM	0.105	0.107	0.106	0.102	0.103	0.104	0.104	0.103	0.105	0.103	0.104	0.002	1.5
11/17/94	9:30 AM	0.102	0.103	0.105	0.107	0.106	0.107	0.107	0.106	0.103	0.105	0.105	0.002	1.8
11/17/94	10:00 AM	0.103	0.107	0.107	0.105	0.107	0.104	0.106	0.103	0.104	0.107	0.105	0.002	1.6
11/17/94	10:30 AM	0.108	0.102	0.106	0.107	0.107	0.104	0.103	0.103	0.103	0.107	0.105	0.002	2.1
11/17/94	11:35 AM	0.104	0.106	0.106	0.101	0.108	0.102	0.107	0.106	0.103	0.103	0.105	0.002	2.2
11/17/94	12:05 PM	0.107	0.106	0.104	0.104	0.107	0.104	0.107	0.107	0.102	0.103	0.105	0.002	1.8
11/17/94	12:35 PM	0.101	0.107	0.102	0.102	0.107	0.101	0.105	0.107	0.102	0.105	0.104	0.003	2.5
11/17/94	1:45 PM	0.106	0.107	0.103	0.106	0.104	0.102	0.107	0.106	0.104	0.103	0.105	0.002	1.7
11/17/94	2:35 PM	0.103	0.103	0.105	0.105	0.107	0.108	0.105	0.105	0.106	0.107	0.106	0.002	1.6
11/17/94	3:05 PM	0.106	0.106	0.102	0.104	0.103	0.104	0.105	0.107	0.103	0.106	0.105	0.002	1.6
11/17/94	3:30 PM	0.102	0.104	0.105	0.106	0.107	0.105	0.107	0.104	0.106	0.106	0.105	0.002	1.5
11/17/94	4:00 PM	0.107	0.103	0.104	0.104	0.108	0.103	0.107	0.106	0.105	0.104	0.105	0.002	1.7
11/17/94	4:30 PM	0.106	0.107	0.103	0.104	0.104	0.105	0.104	0.103	0.106	0.104	0.105	0.001	1.3
11/17/94	5:05 PM	0.105	0.104	0.107	0.108	0.106	0.104	0.101	0.108	0.106	0.107	0.106	0.002	2.1
11/17/94	5:35 PM	0.103	0.106	0.103	0.106	0.107	0.102	0.102	0.104	0.105	0.108	0.105	0.002	2.0
11/17/94	6:25 PM	0.101	0.108	0.106	0.107	0.103	0.107	0.108	0.105	0.107	0.105	0.106	0.002	2.1
11/17/94	6:55 PM	0.103	0.108	0.101	0.106	0.107	0.104	0.106	0.106	0.103	0.106	0.105	0.002	2.1



AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION**

DIGOXIN TABLETS, 0.125 mg - Batch # 4318A

Compression - Hardness (kp) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/11/94	1:50 PM	4.2	3.8	5.0	4.5	4.5	4.4	0.4	10.0
11/11/94	2:45 PM	4.1	4.5	5.0	4.4	4.3	4.5	0.3	7.5
11/11/94	3:20 PM	4.4	4.6	4.6	4.6	4.7	4.6	0.1	2.4
11/11/94	4:00 PM	4.4	4.6	4.7	4.6	4.7	4.6	0.1	2.7
11/11/94	4:30 PM	5.1	4.6	4.5	5.0	5.2	4.9	0.3	6.4
11/12/94	7:25 AM	4.6	4.5	4.2	4.7	4.6	4.5	0.2	4.3
11/12/94	7:55 AM	4.4	5.1	4.7	4.8	4.5	4.7	0.3	5.8
11/12/94	8:25 AM	4.4	4.5	4.2	5.2	3.9	4.4	0.5	10.9
11/12/94	8:55 AM	4.8	4.7	4.5	4.3	4.6	4.6	0.2	4.2
11/12/94	9:25 AM	4.6	4.3	4.8	4.3	4.5	4.5	0.2	4.7
11/12/94	9:55 AM	4.8	4.5	4.2	4.2	4.3	4.4	0.3	5.8
11/12/94	10:25 AM	4.8	4.9	4.5	4.4	4.4	4.6	0.2	5.1
11/12/94	11:50 AM	4.7	4.8	4.2	4.2	4.5	4.5	0.3	6.2
11/12/94	12:20 PM	5.0	4.4	4.8	4.2	4.7	4.6	0.3	6.9
11/12/94	12:50 PM	4.8	4.5	4.6	4.4	4.2	4.5	0.2	5.0
11/12/94	1:20 PM	4.7	4.6	4.9	4.4	4.1	4.5	0.3	6.7
11/12/94	1:50 PM	4.5	4.5	4.7	4.5	4.7	4.6	0.1	2.4
11/12/94	2:20 PM	4.4	4.6	4.4	5.1	5.0	4.7	0.3	7.1
11/14/94	8:20 AM	4.0	3.9	3.7	4.3	4.1	4.0	0.2	5.6
11/14/94	8:45 AM	4.2	4.3	4.2	4.2	4.0	4.2	0.1	2.6
11/14/94	9:15 AM	4.3	4.2	4.4	4.3	4.6	4.4	0.2	3.5
11/14/94	9:45 AM	4.4	4.0	3.9	4.4	4.4	4.2	0.2	5.9
11/14/94	10:15 AM	4.3	4.3	4.2	4.3	3.9	4.2	0.2	4.1
11/14/94	10:45 AM	4.4	4.7	4.5	4.3	4.6	4.5	0.2	3.5
11/14/94	1:25 PM	3.9	4.4	4.0	4.1	4.3	4.1	0.2	5.0
11/14/94	1:50 PM	4.0	4.9	4.2	4.3	4.3	4.3	0.3	7.7
11/14/94	2:45 PM	4.3	4.5	4.7	3.7	4.6	4.4	0.4	9.1

Compression - Hardness (kp) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/11/94	1:50 PM	4.5	3.6	4.3	4.6	4.2	4.2	0.4	9.2
11/11/94	2:45 PM	4.3	3.7	4.5	4.6	4.6	4.3	0.4	8.7
11/11/94	3:20 PM	4.5	4.9	4.1	4.7	4.9	4.6	0.3	7.2
11/11/94	4:00 PM	4.8	3.9	4.4	4.0	5.0	4.4	0.5	10.9
11/11/94	4:30 PM	4.5	4.0	4.2	4.5	4.6	4.4	0.3	5.8
11/12/94	7:25 AM	4.7	5.1	4.4	4.7	5.4	4.9	0.4	8.0
11/12/94	7:55 AM	4.4	4.2	4.4	4.6	4.4	4.4	0.1	3.2
11/12/94	8:25 AM	3.9	5.0	4.3	5.3	3.7	4.4	0.7	15.6
11/12/94	8:55 AM	4.5	5.3	4.1	5.0	4.7	4.7	0.5	9.8
11/12/94	9:25 AM	4.4	4.1	4.5	5.3	4.1	4.5	0.5	11.0
11/12/94	9:55 AM	4.6	5.4	4.4	4.6	5.1	4.8	0.4	8.6
11/12/94	10:25 AM	4.6	5.0	4.7	4.1	3.8	4.4	0.5	10.9
11/12/94	11:50 AM	5.0	4.1	4.3	4.2	4.7	4.5	0.4	8.5
11/12/94	12:20 PM	5.4	5.0	4.3	4.2	4.2	4.6	0.5	11.9
11/12/94	12:50 PM	4.5	4.4	4.6	5.4	4.6	4.7	0.4	8.5
11/12/94	1:20 PM	5.0	4.5	5.0	4.6	4.4	4.7	0.3	6.0
11/12/94	1:50 PM	4.6	4.4	5.1	5.0	4.9	4.8	0.3	6.1
11/12/94	2:20 PM	5.2	4.4	4.2	4.4	5.0	4.6	0.4	9.3
11/14/94	8:20 AM	4.8	4.0	4.2	4.0	4.3	4.3	0.3	7.7
11/14/94	8:45 AM	4.0	4.5	4.0	4.0	4.4	4.2	0.2	6.0
11/14/94	9:15 AM	4.3	4.5	4.5	4.6	4.5	4.5	0.1	2.4
11/14/94	9:45 AM	4.8	4.6	4.6	4.6	4.5	4.6	0.1	2.4
11/14/94	10:15 AM	4.2	4.5	4.7	4.9	4.3	4.5	0.3	6.3
11/14/94	10:45 AM	4.1	4.4	4.2	4.2	3.9	4.2	0.2	4.4
11/14/94	1:25 PM	4.4	4.2	3.8	4.2	4.3	4.2	0.2	5.5
11/14/94	1:50 PM	4.5	4.1	4.7	4.9	4.2	4.5	0.3	7.5
11/14/94	2:45 PM	3.7	4.7	3.6	4.4	4.4	4.2	0.5	11.6

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg - Batch # 4320A**

Compression - Hardness (kp) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/14/94	5:15 PM	4.4	4.7	4.8	4.4	4.4	4.5	0.2	4.3
11/14/94	5:45 PM	4.6	4.1	4.7	4.3	4.3	4.4	0.2	5.6
11/14/94	6:15 PM	4.6	5.0	4.5	4.9	4.3	4.7	0.3	6.2
11/14/94	6:45 PM	4.2	4.3	4.5	4.2	4.2	4.3	0.1	3.0
11/14/94	7:15 PM	4.3	4.6	4.0	4.2	4.6	4.3	0.3	6.0
11/14/94	7:45 PM	5.2	4.5	4.2	5.0	4.6	4.7	0.4	8.5
11/14/94	8:15 PM	4.7	4.6	5.0	4.2	4.8	4.7	0.3	6.4
11/14/94	8:45 PM	5.3	4.8	4.7	5.7	4.5	5.0	0.5	9.8
11/15/94	8:00 AM	4.5	4.6	4.3	4.3	4.7	4.5	0.2	4.0
11/15/94	8:30 AM	4.6	4.3	4.4	4.8	4.3	4.5	0.2	4.8
11/15/94	9:00 AM	4.7	4.5	4.4	4.3	4.4	4.5	0.2	3.4
11/15/94	9:30 AM	4.5	4.8	4.5	4.5	4.5	4.6	0.1	2.9
11/15/94	10:00 AM	4.6	4.2	4.6	5.0	4.3	4.5	0.3	6.9
11/15/94	10:30 AM	4.2	4.9	4.8	5.1	4.8	4.8	0.3	7.1
11/15/94	11:35 AM	4.4	4.9	4.2	4.4	4.6	4.5	0.3	5.9
11/15/94	12:05 PM	4.2	4.3	4.2	4.8	4.5	4.4	0.3	5.8
11/15/94	12:35 PM	4.0	4.7	4.2	4.2	3.9	4.2	0.3	7.3
11/15/94	1:05 PM	4.6	4.6	4.5	4.4	4.8	4.6	0.1	3.2
11/15/94	1:35 PM	4.4	4.6	4.7	5.3	4.9	4.8	0.3	7.2
11/15/94	4:30 PM	4.7	4.3	4.3	5.0	4.5	4.6	0.3	6.5
11/15/94	5:00 PM	4.3	4.4	4.8	4.3	4.3	4.4	0.2	4.9
11/15/94	5:30 PM	4.7	4.5	5.2	4.5	4.8	4.7	0.3	6.1
11/15/94	6:10 PM	4.7	4.2	4.4	4.8	4.8	4.6	0.3	5.9
11/15/94	6:40 PM	4.5	4.3	4.4	4.8	4.3	4.5	0.2	4.6
11/15/94	7:10 PM	4.6	4.4	4.7	4.4	4.3	4.5	0.2	3.7
11/15/94	7:40 PM	4.8	4.3	4.8	4.3	4.4	4.5	0.3	5.7
11/15/94	8:10 PM	4.7	4.2	4.0	4.5	4.4	4.4	0.3	6.2
11/15/94	8:40 PM	4.7	5.2	4.4	5.0	4.6	4.8	0.3	6.7
11/15/94	9:10 PM	4.8	4.6	5.1	4.1	4.5	4.6	0.4	8.0

Compression - Hardness (kp) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/14/94	5:15 PM	3.9	3.9	3.7	4.4	4.7	4.1	0.4	10.1
11/14/94	5:45 PM	4.1	4.2	4.9	4.6	4.1	4.1	0.4	8.1
11/14/94	6:15 PM	4.3	4.6	3.9	4.7	3.4	4.2	0.5	12.8
11/14/94	6:45 PM	4.1	3.9	3.7	4.0	4.1	4.0	0.2	4.2
11/14/94	7:15 PM	4.7	4.0	3.9	4.6	4.2	4.3	0.4	8.3
11/14/94	7:45 PM	4.8	4.4	4.5	4.7	4.7	4.6	0.2	3.6
11/14/94	8:15 PM	5.4	5.8	4.3	5.6	4.9	5.2	0.6	11.6
11/14/94	8:45 PM	5.3	5.4	4.3	4.9	4.8	4.9	0.4	8.9
11/15/94	8:00 AM	4.2	3.7	4.4	4.8	4.9	4.4	0.5	11.0
11/15/94	8:30 AM	3.7	3.9	3.8	3.9	4.9	4.0	0.5	12.1
11/15/94	9:00 AM	4.8	4.2	3.9	4.5	4.8	4.4	0.4	8.8
11/15/94	9:30 AM	4.1	4.6	4.7	4.9	4.0	4.5	0.4	8.8
11/15/94	10:00 AM	4.5	4.2	4.2	4.2	4.1	4.2	0.2	3.6
11/15/94	10:30 AM	4.6	4.7	4.9	5.0	4.5	4.7	0.2	4.4
11/15/94	11:35 AM	3.7	4.1	4.7	4.1	4.6	4.2	0.4	9.7
11/15/94	12:05 PM	4.8	4.4	4.8	4.3	3.9	4.4	0.4	8.5
11/15/94	12:35 PM	4.0	4.5	4.1	4.7	5.0	4.5	0.4	9.3
11/15/94	1:05 PM	4.3	4.5	4.8	4.4	4.7	4.5	0.2	4.6
11/15/94	1:35 PM	4.7	4.7	4.0	4.6	4.7	4.5	0.3	6.7
11/15/94	4:30 PM	4.2	4.1	4.7	4.3	4.2	4.3	0.2	5.5
11/15/94	5:00 PM	4.8	4.7	5.2	4.6	4.9	4.8	0.2	4.8
11/15/94	5:30 PM	5.1	4.3	4.5	4.1	4.7	4.5	0.4	8.5
11/15/94	6:10 PM	4.4	4.9	4.6	4.4	4.4	4.5	0.2	4.8
11/15/94	6:40 PM	4.7	5.1	4.8	4.1	4.2	4.6	0.4	9.2
11/15/94	7:10 PM	3.9	4.8	4.6	3.7	5.0	4.4	0.6	13.0
11/15/94	7:40 PM	4.8	4.4	4.7	4.7	5.2	4.8	0.3	6.1
11/15/94	8:10 PM	4.9	4.4	4.0	4.7	4.5	4.5	0.3	7.5
11/15/94	8:40 PM	5.2	4.1	4.6	4.5	5.2	4.7	0.5	10.1
11/15/94	9:10 PM	4.0	4.0	4.5	5.2	4.7	4.5	0.5	11.3

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

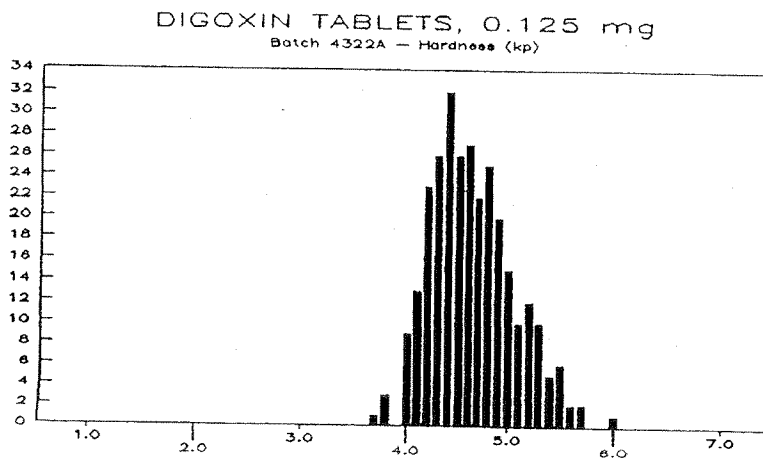
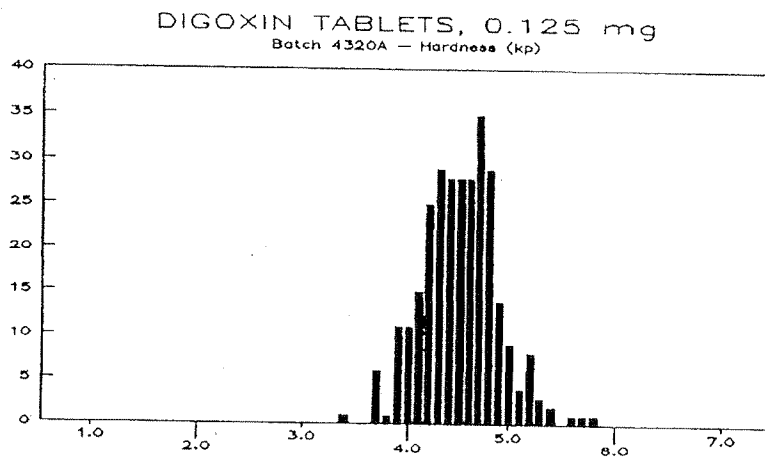
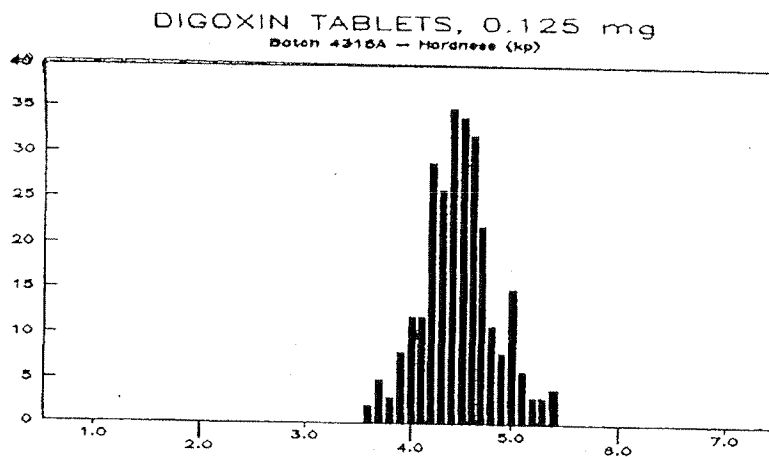
DIGOXIN TABLETS, 0.125 mg - Batch # 4322A

Compression - Hardness (kp) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/16/94	12:15 PM	4.8	4.8	4.5	4.9	4.4	4.7	0.2	1.6
11/16/94	12:45 PM	4.6	4.8	4.3	4.3	4.4	4.5	0.2	4.8
11/16/94	1:15 PM	4.7	4.3	4.8	4.5	4.2	4.5	0.3	5.7
11/16/94	1:45 PM	4.2	4.7	4.4	4.9	4.7	4.6	0.3	6.1
11/16/94	2:30 PM	4.5	5.3	4.7	4.5	5.2	4.8	0.4	7.9
11/16/94	3:00 PM	4.6	4.6	4.3	4.6	5.2	4.7	0.3	7.1
11/16/94	3:35 PM	4.2	4.5	5.2	4.8	4.7	4.7	0.4	7.9
11/16/94	4:05 PM	4.7	4.8	4.4	4.7	5.1	4.7	0.3	5.3
11/16/94	4:35 PM	4.5	4.8	4.5	4.4	4.5	4.5	0.2	3.3
11/16/94	5:05 PM	4.6	4.8	5.0	4.0	4.9	4.7	0.4	8.5
11/17/94	8:00 AM	4.2	4.4	4.3	4.5	4.3	4.3	0.1	2.6
11/17/94	8:30 AM	4.5	4.9	4.3	4.8	4.4	4.6	0.3	5.7
11/17/94	9:00 AM	4.1	4.4	4.5	4.3	4.4	4.3	0.2	3.5
11/17/94	9:30 AM	4.8	4.6	4.6	4.4	4.9	4.7	0.2	4.2
11/17/94	10:00 AM	4.1	4.4	4.0	4.7	4.6	4.4	0.3	7.0
11/17/94	10:30 AM	4.6	4.6	4.9	4.0	4.3	4.5	0.3	7.6
11/17/94	11:35 AM	4.4	4.6	4.4	4.8	5.3	4.7	0.4	8.0
11/17/94	12:05 PM	4.1	4.0	4.7	4.5	4.1	4.3	0.3	7.1
11/17/94	12:35 PM	4.6	4.2	4.2	4.2	5.0	4.4	0.4	8.1
11/17/94	1:45 PM	4.0	5.3	5.4	5.3	4.3	4.9	0.7	13.5
11/17/94	2:35 PM	4.1	4.3	4.2	4.2	4.6	4.3	0.2	4.5
11/17/94	3:05 PM	4.0	4.3	4.9	4.5	4.1	4.4	0.4	8.2
11/17/94	3:30 PM	4.2	4.2	4.2	4.3	4.0	4.2	0.1	2.6
11/17/94	4:00 PM	4.1	4.2	4.3	4.4	4.5	4.3	0.2	3.7
11/17/94	4:30 PM	5.0	4.4	5.0	4.7	4.8	4.8	0.2	5.2
11/17/94	5:05 PM	4.4	4.5	4.5	4.2	4.9	4.5	0.3	5.7
11/17/94	5:35 PM	4.9	4.1	4.4	4.4	4.5	4.5	0.3	6.5
11/17/94	6:25 PM	4.0	5.1	4.5	4.9	4.4	4.6	0.4	9.4
11/17/94	6:55 PM	4.8	4.3	4.5	4.8	5.3	4.7	0.4	8.0

Compression - Hardness (kp) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/16/94	12:15 PM	4.8	5.0	5.3	4.3	5.5	5.0	0.5	9.4
11/16/94	12:45 PM	4.4	4.8	4.7	4.7	4.6	4.6	0.2	3.3
11/16/94	1:15 PM	4.7	5.6	4.7	4.5	4.5	4.8	0.5	9.5
11/16/94	1:45 PM	5.4	4.9	5.0	5.2	5.2	5.1	0.2	3.8
11/16/94	2:30 PM	4.6	5.6	5.3	5.1	4.4	5.0	0.5	9.9
11/16/94	3:00 PM	5.3	4.9	4.4	5.7	4.7	5.0	0.5	10.2
11/16/94	3:35 PM	4.7	4.9	4.6	5.1	4.5	4.8	0.2	5.1
11/16/94	4:05 PM	5.2	4.4	5.2	5.0	4.6	4.9	0.4	7.4
11/16/94	4:35 PM	4.3	4.9	4.7	5.2	4.8	4.8	0.3	6.8
11/16/94	5:05 PM	5.1	4.7	5.5	5.0	5.2	5.1	0.3	5.7
11/17/94	8:00 AM	4.1	5.4	6.0	5.3	5.5	5.3	0.7	13.3
11/17/94	8:30 AM	4.6	4.3	4.7	5.7	4.9	4.8	0.5	10.9
11/17/94	9:00 AM	4.9	5.3	4.3	4.3	4.1	4.6	0.5	11.0
11/17/94	9:30 AM	5.1	4.9	4.8	4.6	4.9	4.9	0.2	3.7
11/17/94	10:00 AM	4.1	4.4	4.2	4.8	5.4	4.6	0.5	11.6
11/17/94	10:30 AM	4.3	5.2	4.2	4.7	4.8	4.6	0.4	8.7
11/17/94	11:35 AM	5.0	5.0	4.1	5.5	4.6	4.8	0.5	10.8
11/17/94	12:05 PM	5.2	4.4	4.8	4.2	4.3	4.6	0.4	9.1
11/17/94	12:35 PM	4.7	3.7	4.5	3.8	5.0	4.3	0.6	13.1
11/17/94	1:45 PM	4.1	4.6	4.2	4.3	4.5	4.3	0.2	4.8
11/17/94	2:35 PM	4.9	4.2	5.0	5.2	4.3	4.7	0.4	9.4
11/17/94	3:05 PM	3.8	5.1	3.8	4.8	4.6	4.4	0.6	13.4
11/17/94	3:30 PM	4.4	4.2	4.3	5.4	4.2	4.5	0.5	11.3
11/17/94	4:00 PM	4.6	4.3	4.4	4.2	4.8	4.5	0.2	5.4
11/17/94	4:30 PM	4.8	4.5	4.7	5.0	4.4	4.7	0.2	5.1
11/17/94	5:05 PM	5.1	5.1	4.6	5.1	4.9	5.0	0.2	4.4
11/17/94	5:35 PM	4.6	5.0	4.4	4.4	4.6	4.6	0.2	5.3
11/17/94	6:25 PM	4.5	4.4	4.6	4.2	5.0	4.5	0.3	6.5
11/17/94	6:55 PM	4.4	5.5	4.0	4.8	5.5	4.8	0.7	13.8



AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION**

DIGOXIN TABLETS, 0.125 mg - Batch # 4318A

Compression - Thickness (mm) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/11/94	1:50 PM	2.66	2.66	2.65	2.62	2.65	2.65	0.02	0.6
11/11/94	2:45 PM	2.62	2.62	2.63	2.64	2.60	2.62	0.01	0.6
11/11/94	3:20 PM	2.67	2.65	2.63	2.64	2.65	2.65	0.01	0.6
11/11/94	4:00 PM	2.61	2.63	2.68	2.64	2.59	2.63	0.03	1.3
11/11/94	4:30 PM	2.66	2.64	2.64	2.64	2.63	2.64	0.01	0.4
11/12/94	7:25 AM	2.60	2.69	2.68	2.67	2.66	2.66	0.03	1.3
11/12/94	7:55 AM	2.71	2.70	2.69	2.70	2.65	2.69	0.02	0.9
11/12/94	8:25 AM	2.64	2.64	2.66	2.62	2.66	2.64	0.02	0.6
11/12/94	8:55 AM	2.66	2.69	2.63	2.63	2.61	2.64	0.03	1.1
11/12/94	9:25 AM	2.63	2.65	2.65	2.65	2.64	2.64	0.01	0.3
11/12/94	9:55 AM	2.68	2.66	2.61	2.63	2.63	2.64	0.03	1.1
11/12/94	10:25 AM	2.63	2.67	2.61	2.67	2.63	2.64	0.03	1.0
11/12/94	11:50 AM	2.66	2.60	2.67	2.63	2.65	2.64	0.03	1.1
11/12/94	12:20 PM	2.63	2.59	2.59	2.62	2.67	2.62	0.03	1.3
11/12/94	12:50 PM	2.63	2.66	2.62	2.61	2.64	2.63	0.02	0.7
11/12/94	1:20 PM	2.62	2.61	2.61	2.65	2.61	2.62	0.02	0.7
11/12/94	1:50 PM	2.64	2.61	2.62	2.59	2.63	2.62	0.02	0.7
11/12/94	2:20 PM	2.60	2.60	2.63	2.64	2.60	2.61	0.02	0.7
11/14/94	8:20 AM	2.62	2.61	2.67	2.63	2.63	2.63	0.02	0.9
11/14/94	8:45 AM	2.64	2.62	2.63	2.60	2.65	2.63	0.02	0.7
11/14/94	9:15 AM	2.61	2.65	2.65	2.63	2.65	2.64	0.02	0.7
11/14/94	9:45 AM	2.64	2.61	2.59	2.63	2.62	2.62	0.02	0.7
11/14/94	10:15 AM	2.64	2.62	2.63	2.62	2.62	2.63	0.01	0.3
11/14/94	10:45 AM	2.59	2.66	2.63	2.63	2.63	2.63	0.02	0.9
11/14/94	1:25 PM	2.61	2.66	2.61	2.64	2.61	2.63	0.02	0.9
11/14/94	1:50 PM	2.64	2.62	2.61	2.58	2.59	2.61	0.02	0.9
11/14/94	2:45 PM	2.64	2.65	2.59	2.63	2.63	2.63	0.02	0.9

Compression - Thickness (mm) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/11/94	1:50 PM	2.57	2.59	2.63	2.62	2.64	2.61	0.03	1.1
11/11/94	2:45 PM	2.58	2.63	2.59	2.64	2.63	2.61	0.03	1.0
11/11/94	3:20 PM	2.61	2.60	2.64	2.63	2.64	2.62	0.02	0.7
11/11/94	4:00 PM	2.61	2.65	2.61	2.62	2.58	2.61	0.03	1.0
11/11/94	4:30 PM	2.62	2.65	2.55	2.65	2.62	2.62	0.04	1.6
11/12/94	7:25 AM	2.66	2.64	2.65	2.67	2.68	2.66	0.02	0.6
11/12/94	7:55 AM	2.60	2.65	2.66	2.66	2.63	2.64	0.03	1.0
11/12/94	8:25 AM	2.65	2.64	2.59	2.68	2.60	2.63	0.04	1.4
11/12/94	8:55 AM	2.67	2.66	2.66	2.68	2.65	2.66	0.01	0.4
11/12/94	9:25 AM	2.64	2.58	2.61	2.61	2.59	2.61	0.02	0.9
11/12/94	9:55 AM	2.62	2.66	2.68	2.66	2.62	2.65	0.03	1.0
11/12/94	10:25 AM	2.59	2.60	2.65	2.63	2.64	2.62	0.03	1.0
11/12/94	11:50 AM	2.68	2.63	2.66	2.62	2.66	2.65	0.02	0.9
11/12/94	12:20 PM	2.60	2.63	2.65	2.63	2.65	2.63	0.02	0.8
11/12/94	12:50 PM	2.64	2.61	2.67	2.62	2.61	2.63	0.03	1.0
11/12/94	1:20 PM	2.62	2.63	2.63	2.61	2.68	2.63	0.03	1.0
11/12/94	1:50 PM	2.64	2.62	2.63	2.65	2.65	2.64	0.01	0.5
11/12/94	2:20 PM	2.63	2.60	2.59	2.63	2.64	2.62	0.02	0.8
11/14/94	8:20 AM	2.64	2.63	2.61	2.65	2.66	2.64	0.02	0.7
11/14/94	8:45 AM	2.61	2.64	2.59	2.63	2.62	2.62	0.02	0.7
11/14/94	9:15 AM	2.63	2.63	2.64	2.59	2.65	2.63	0.02	0.9
11/14/94	9:45 AM	2.63	2.66	2.63	2.63	2.64	2.64	0.01	0.5
11/14/94	10:15 AM	2.60	2.61	2.63	2.57	2.60	2.60	0.02	0.8
11/14/94	10:45 AM	2.60	2.57	2.60	2.58	2.57	2.58	0.02	0.6
11/14/94	1:25 PM	2.64	2.61	2.62	2.60	2.65	2.62	0.02	0.8
11/14/94	1:50 PM	2.60	2.69	2.64	2.63	2.61	2.63	0.04	1.3
11/14/94	2:45 PM	2.66	2.58	2.63	2.62	2.58	2.61	0.03	1.3

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 4320A

Compression - Thickness (mm) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/14/94	5:15 PM	2.62	2.65	2.66	2.68	2.65	2.65	0.02	0.8
11/14/94	5:45 PM	2.64	2.60	2.64	2.61	2.64	2.63	0.02	0.7
11/14/94	6:15 PM	2.67	2.61	2.61	2.66	2.63	2.64	0.03	1.1
11/14/94	6:45 PM	2.66	2.59	2.62	2.59	2.60	2.61	0.03	1.1
11/14/94	7:15 PM	2.62	2.61	2.58	2.61	2.64	2.61	0.02	0.8
11/14/94	7:45 PM	2.62	2.62	2.64	2.65	2.62	2.63	0.01	0.5
11/14/94	8:15 PM	2.63	2.66	2.64	2.66	2.69	2.66	0.02	0.9
11/14/94	8:45 PM	2.64	2.68	2.69	2.63	2.63	2.65	0.03	1.1
11/15/94	8:00 AM	2.66	2.68	2.67	2.68	2.65	2.67	0.01	0.5
11/15/94	8:30 AM	2.65	2.65	2.61	2.64	2.62	2.64	0.02	0.8
11/15/94	9:00 AM	2.64	2.60	2.61	2.63	2.64	2.62	0.02	0.7
11/15/94	9:30 AM	2.65	2.65	2.63	2.67	2.60	2.64	0.03	1.0
11/15/94	10:00 AM	2.58	2.58	2.59	2.61	2.60	2.59	0.01	0.5
11/15/94	10:30 AM	2.64	2.64	2.62	2.64	2.63	2.63	0.01	0.3
11/15/94	11:35 AM	2.62	2.62	2.65	2.64	2.68	2.64	0.02	0.9
11/15/94	12:05 PM	2.62	2.62	2.63	2.60	2.60	2.61	0.01	0.5
11/15/94	12:35 PM	2.63	2.62	2.62	2.62	2.66	2.63	0.02	0.7
11/15/94	1:05 PM	2.61	2.61	2.62	2.64	2.64	2.62	0.02	0.6
11/15/94	1:35 PM	2.63	2.64	2.65	2.64	2.61	2.63	0.02	0.6
11/15/94	4:30 PM	2.64	2.67	2.65	2.63	2.64	2.65	0.02	0.6
11/15/94	5:00 PM	2.64	2.66	2.63	2.66	2.64	2.65	0.01	0.5
11/15/94	5:30 PM	2.62	2.62	2.63	2.64	2.62	2.63	0.01	0.3
11/15/94	6:10 PM	2.60	2.63	2.62	2.63	2.66	2.63	0.02	0.8
11/15/94	6:40 PM	2.61	2.60	2.63	2.64	2.63	2.62	0.02	0.6
11/15/94	7:10 PM	2.63	2.60	2.60	2.63	2.59	2.61	0.02	0.7
11/15/94	7:40 PM	2.65	2.63	2.61	2.65	2.65	2.64	0.02	0.7
11/15/94	8:10 PM	2.59	2.62	2.61	2.60	2.59	2.60	0.01	0.5
11/15/94	8:40 PM	2.62	2.63	2.56	2.62	2.60	2.61	0.03	1.1
11/15/94	9:10 AM	2.62	2.64	2.59	2.61	2.63	2.62	0.02	0.7

Compression - Thickness (mm) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/14/94	5:15 PM	2.61	2.62	2.67	2.58	2.58	2.61	0.04	1.4
11/14/94	5:45 PM	2.64	2.61	2.63	2.63	2.61	2.62	0.01	0.5
11/14/94	6:15 PM	2.56	2.65	2.61	2.64	2.55	2.60	0.05	1.7
11/14/94	6:45 PM	2.54	2.57	2.56	2.59	2.59	2.57	0.02	0.8
11/14/94	7:15 PM	2.60	2.59	2.55	2.58	2.60	2.58	0.02	0.8
11/14/94	7:45 PM	2.66	2.63	2.65	2.61	2.60	2.63	0.03	1.0
11/14/94	8:15 PM	2.60	2.66	2.69	2.65	2.67	2.65	0.03	1.3
11/14/94	8:45 PM	2.67	2.66	2.62	2.64	2.60	2.64	0.03	1.1
11/15/94	8:00 AM	2.64	2.61	2.62	2.68	2.66	2.64	0.03	1.1
11/15/94	8:30 AM	2.59	2.63	2.58	2.61	2.57	2.60	0.02	0.9
11/15/94	9:00 AM	2.56	2.63	2.62	2.63	2.60	2.61	0.03	1.1
11/15/94	9:30 AM	2.61	2.63	2.57	2.61	2.63	2.61	0.02	0.9
11/15/94	10:00 AM	2.63	2.61	2.63	2.65	2.59	2.62	0.02	0.9
11/15/94	10:30 AM	2.62	2.67	2.59	2.61	2.60	2.62	0.03	1.2
11/15/94	11:35 AM	2.63	2.64	2.59	2.57	2.58	2.60	0.03	1.2
11/15/94	12:05 PM	2.66	2.60	2.61	2.66	2.65	2.64	0.03	1.1
11/15/94	12:35 PM	2.62	2.59	2.61	2.64	2.58	2.61	0.02	0.9
11/15/94	1:05 PM	2.63	2.62	2.56	2.59	2.61	2.60	0.03	1.1
11/15/94	1:35 PM	2.58	2.62	2.62	2.65	2.65	2.62	0.03	1.1
11/15/94	4:30 PM	2.59	2.64	2.65	2.61	2.62	2.62	0.02	0.9
11/15/94	5:00 PM	2.63	2.63	2.65	2.62	2.64	2.63	0.01	0.4
11/15/94	5:30 PM	2.57	2.60	2.64	2.60	2.61	2.60	0.03	1.0
11/15/94	6:10 PM	2.63	2.61	2.57	2.59	2.59	2.60	0.02	0.9
11/15/94	6:40 PM	2.61	2.60	2.62	2.59	2.61	2.61	0.01	0.4
11/15/94	7:10 PM	2.62	2.55	2.55	2.60	2.57	2.58	0.03	1.2
11/15/94	7:40 PM	2.65	2.62	2.64	2.62	2.61	2.63	0.02	0.6
11/15/94	8:10 PM	2.60	2.61	2.58	2.57	2.62	2.60	0.02	0.8
11/15/94	8:40 PM	2.55	2.59	2.61	2.61	2.60	2.59	0.02	1.0
11/15/94	9:10 AM	2.60	2.56	2.55	2.58	2.55	2.57	0.02	0.8

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION**

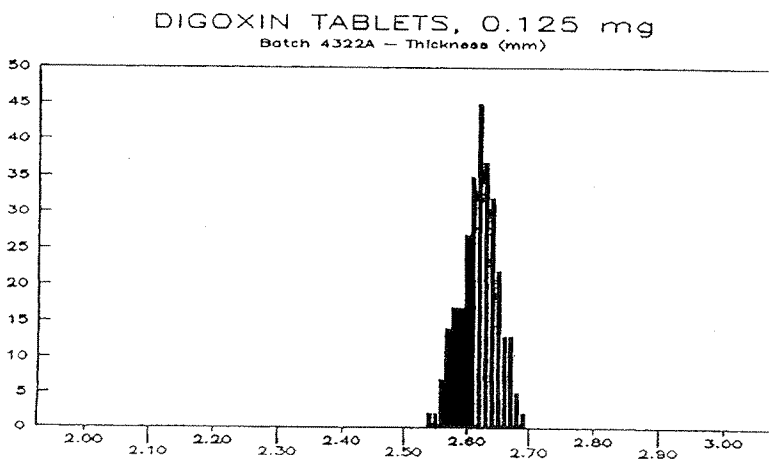
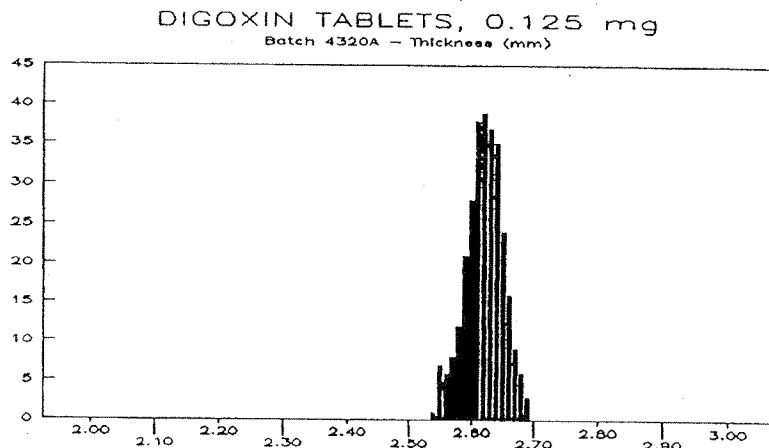
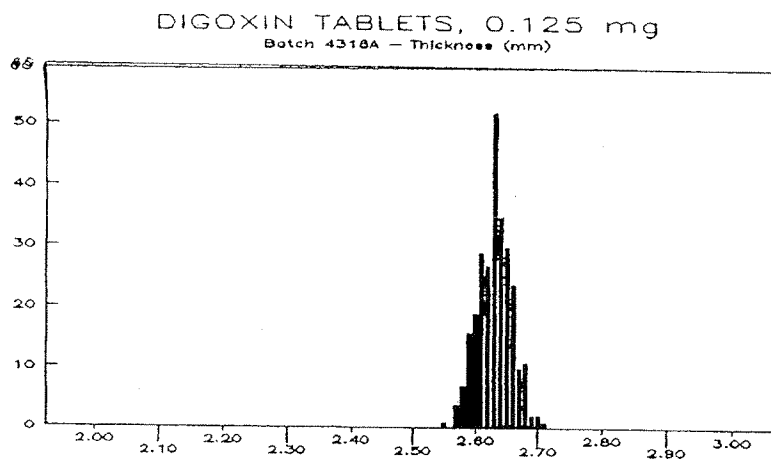
DIGOXIN TABLETS, 0.125 mg - Batch # 4322A

Compression - Thickness (mm) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/16/94	12:15 PM	2.64	2.64	2.69	2.64	2.66	2.65	0.02	0.8
11/16/94	12:45 PM	2.64	2.63	2.66	2.63	2.67	2.65	0.02	0.7
11/16/94	1:15 PM	2.67	2.64	2.62	2.65	2.65	2.65	0.02	0.7
11/16/94	1:45 PM	2.61	2.62	2.63	2.67	2.62	2.63	0.02	0.9
11/16/94	2:30 PM	2.64	2.64	2.62	2.58	2.63	2.62	0.02	0.9
11/16/94	3:00 PM	2.63	2.60	2.62	2.63	2.62	2.62	0.01	0.5
11/16/94	3:35 PM	2.61	2.64	2.64	2.63	2.64	2.63	0.01	0.5
11/16/94	4:05 PM	2.65	2.63	2.67	2.65	2.61	2.64	0.02	0.9
11/16/94	4:35 PM	2.65	2.63	2.64	2.62	2.65	2.64	0.01	0.5
11/16/94	5:05 PM	2.63	2.60	2.62	2.62	2.61	2.62	0.01	0.4
11/17/94	8:00 AM	2.64	2.67	2.66	2.64	2.69	2.66	0.02	0.8
11/17/94	8:30 AM	2.67	2.67	2.63	2.67	2.65	2.66	0.02	0.7
11/17/94	9:00 AM	2.63	2.64	2.62	2.63	2.60	2.62	0.02	0.6
11/17/94	9:30 AM	2.62	2.61	2.63	2.61	2.62	2.62	0.01	0.3
11/17/94	10:00 AM	2.57	2.59	2.63	2.63	2.61	2.61	0.03	1.0
11/17/94	10:30 AM	2.62	2.60	2.62	2.62	2.61	2.61	0.01	0.3
11/17/94	11:35 AM	2.64	2.59	2.64	2.61	2.64	2.62	0.02	0.9
11/17/94	12:05 PM	2.61	2.59	2.62	2.59	2.58	2.60	0.02	0.6
11/17/94	12:35 PM	2.62	2.61	2.65	2.61	2.63	2.62	0.02	0.6
11/17/94	1:45 PM	2.63	2.63	2.68	2.64	2.57	2.63	0.04	1.5
11/17/94	2:35 PM	2.66	2.60	2.62	2.62	2.61	2.62	0.02	0.9
11/17/94	3:05 PM	2.65	2.60	2.62	2.59	2.60	2.61	0.02	0.9
11/17/94	3:30 PM	2.60	2.62	2.62	2.62	2.61	2.61	0.01	0.3
11/17/94	4:00 PM	2.61	2.62	2.60	2.60	2.59	2.60	0.01	0.4
11/17/94	4:30 PM	2.64	2.65	2.61	2.59	2.66	2.63	0.03	1.1
11/17/94	5:05 PM	2.60	2.62	2.63	2.61	2.61	2.61	0.01	0.4
11/17/94	5:35 PM	2.62	2.63	2.64	2.59	2.61	2.62	0.02	0.7
11/17/94	6:25 PM	2.63	2.66	2.60	2.66	2.61	2.63	0.03	1.1
11/17/94	6:55 PM	2.64	2.66	2.62	2.62	2.67	2.64	0.02	0.9

Compression - Thickness (mm) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
11/16/94	12:15 PM	2.65	2.67	2.63	2.66	2.63	2.65	0.02	0.7
11/16/94	12:45 PM	2.65	2.63	2.63	2.60	2.60	2.62	0.02	0.8
11/16/94	1:15 PM	2.58	2.65	2.66	2.59	2.61	2.62	0.04	1.4
11/16/94	1:45 PM	2.65	2.60	2.65	2.66	2.64	2.64	0.02	0.9
11/16/94	2:30 PM	2.61	2.63	2.63	2.58	2.55	2.60	0.03	1.3
11/16/94	3:00 PM	2.63	2.58	2.65	2.61	2.62	2.62	0.03	1.0
11/16/94	3:35 PM	2.65	2.59	2.58	2.60	2.61	2.61	0.03	1.0
11/16/94	4:05 PM	2.60	2.63	2.58	2.62	2.67	2.62	0.03	1.3
11/16/94	4:35 PM	2.60	2.56	2.58	2.63	2.61	2.60	0.03	1.0
11/16/94	5:05 PM	2.63	2.60	2.62	2.58	2.65	2.62	0.03	1.0
11/17/94	8:00 AM	2.68	2.67	2.65	2.66	2.62	2.66	0.02	0.9
11/17/94	8:30 AM	2.61	2.64	2.68	2.68	2.67	2.66	0.03	1.1
11/17/94	9:00 AM	2.62	2.57	2.57	2.63	2.60	2.60	0.03	1.1
11/17/94	9:30 AM	2.63	2.61	2.62	2.64	2.57	2.61	0.03	1.0
11/17/94	10:00 AM	2.59	2.59	2.64	2.64	2.57	2.61	0.03	1.2
11/17/94	10:30 AM	2.57	2.62	2.61	2.57	2.61	2.60	0.02	0.9
11/17/94	11:35 AM	2.58	2.62	2.62	2.56	2.57	2.59	0.03	1.1
11/17/94	12:05 PM	2.57	2.56	2.61	2.56	2.63	2.59	0.03	1.2
11/17/94	12:35 PM	2.62	2.54	2.58	2.54	2.62	2.58	0.04	1.6
11/17/94	1:45 PM	2.65	2.60	2.64	2.64	2.61	2.63	0.02	0.8
11/17/94	2:35 PM	2.60	2.65	2.58	2.60	2.65	2.62	0.03	1.2
11/17/94	3:05 PM	2.58	2.62	2.59	2.61	2.56	2.59	0.02	0.9
11/17/94	3:30 PM	2.62	2.64	2.60	2.59	2.56	2.60	0.03	1.2
11/17/94	4:00 PM	2.62	2.58	2.56	2.58	2.64	2.60	0.03	1.3
11/17/94	4:30 PM	2.58	2.64	2.63	2.61	2.63	2.62	0.02	0.9
11/17/94	5:05 PM	2.61	2.57	2.59	2.66	2.62	2.61	0.03	1.3
11/17/94	5:35 PM	2.60	2.57	2.57	2.59	2.55	2.58	0.02	0.9
11/17/94	6:25 PM	2.62	2.60	2.58	2.61	2.59	2.60	0.02	0.6
11/17/94	6:55 PM	2.68	2.60	2.62	2.64	2.57	2.62	0.04	1.6



AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Compression - Friability (%)

Batch #	4318A	4318A	4320A	4320A	4320A	4322A	4322A
Side	Front	Rear	Front	Rear	Front	Front	Rear
1st Third	0.1	0.1	0.04	0.1	0.1	0.1	0.1
2nd Third	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Final Third	0.1	0.03	0.1	0.04	0.04	0.04	0.03
Average	0.10	0.08	0.08	0.08	0.08	0.08	0.08
St. Dev.	0.00	0.04	0.03	0.03	0.03	0.03	0.04
RSD	0.0	52.7	43.3	43.3	43.3	43.3	52.7

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg

Compression - Disintegration (min.)

Batch #	4318A	4318A	4320A	4320A	4320A	4322A	4322A
Side	Front	Rear	Front	Rear	Front	Rear	Rear
1st Third	3	3	4	3	3	3	3
2nd Third	3	3	3	3	3	3	3
Final Third	3	4	3	4	4	4	4
Average	3.0	3.3	3.3	3.3	3.3	3.3	3.3
St. Dev.	0.0	0.6	0.6	0.6	0.6	0.6	0.6
RSD	0.0	17.3	17.3	17.3	17.3	17.3	17.3

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION*****DIGOXIN TABLETS, 0.125 mg***

Compression - Content Uniformity (%)

Batch #	4318A	4318A	4320A	4320A	4322A	4322A
Side	Front	Rear	Front	Rear	Front	Rear
1	100.6	99.5	102.8	101.4	101.7	102.9
2	101.1	102.2	96.2	100.5	104.6	97.9
3	103.5	102.9	101.2	101.7	101.0	99.1
4	100.9	101.5	101.4	99.8	102.5	99.3
5	101.9	101.1	100.6	99.0	103.1	99.8
6	101.6	102.4	99.6	99.6	101.6	99.1
7	100.1	98.9	99.3	100.8	102.3	99.9
8	101.4	101.8	99.9	100.9	99.6	100.5
9	101.9	102.6	100.0	102.0	100.1	102.0
10	101.4	102.4	99.3	97.3	104.2	101.4
11	102.3	101.1	98.0	101.2	102.9	100.7
12	99.8	101.6	98.7	99.4	103.4	100.2
13	101.4	98.9	100.8	97.4	102.1	101.5
14	102.2	102.0	101.6	98.6	100.9	99.4
15	101.8	102.0	101.0	100.7	102.6	100.6
16	101.2	103.6	99.1	100.6	101.1	99.3
17	101.5	101.2	98.0	100.3	103.3	102.1
18	99.9	101.4	100.1	100.1	104.8	102.1
19	103.5	102.4	100.2	99.7	103.5	99.3
20	102.4	100.7	93.8	100.6	103.9	101.4
21	100.8	101.0	102.0	100.7	102.7	98.9
22	100.9	100.8	103.1	100.3	103.9	99.8
23	98.7	99.7	102.3	99.8	102.6	99.2
24	100.9	100.9	103.8	100.5	103.2	100.5
25	102.1	100.6	101.2	102.3	102.1	99.6
26	101.7	99.9	101.0	99.9	100.1	101.0
27	100.4	101.0	102.3	101.0	101.3	102.0
28	101.0	101.2	102.9	100.6	100.0	98.9
29	101.1	102.2	99.0	101.2	98.6	100.7
30	103.2	100.1	103.6	101.5	102.0	101.6
Average	101.4	101.3	100.4	100.3	102.2	100.4
St Dev.	1.1	1.2	2.2	1.2	1.5	1.2
RSD	1.0	1.1	2.2	1.2	1.5	1.2

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg

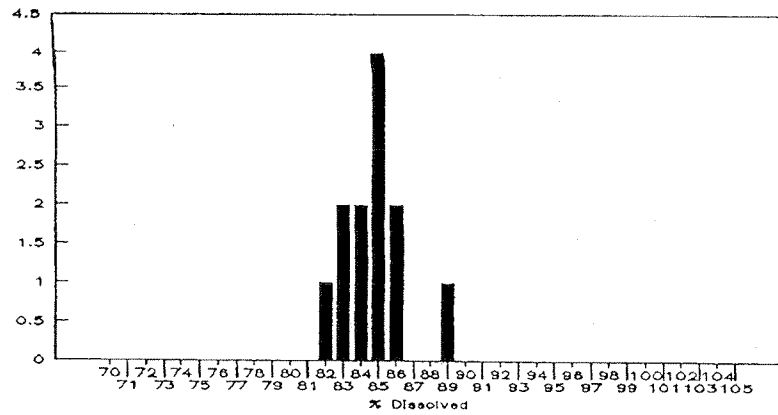
Compression - Dissolution (%) - 15 min.

Batch #	4318A			4318A			4320A			4320A			4322A			4322A		
Sample	1st	Thrd	2nd	Thrd	Final	Thrd	1st	Thrd	2nd	Thrd	Final	Thrd	1st	Thrd	2nd	Thrd	Final	Thrd
1	84.7	81.8	81.2	82.3	83.1	85.8	87.5	81.6	87.0	81.7	81.2	81.5	81.6	81.7	81.2	81.2	81.5	81.5
2	88.1	81.2	81.2	82.3	82.7	84.3	87.0	81.7	82.3	81.7	81.2	81.5	81.6	81.7	81.2	81.2	81.5	81.5
3	84.5	81.3	81.3	82.3	85.0	84.7	82.3	81.7	82.3	81.7	81.2	81.5	81.6	81.7	81.2	81.2	81.5	81.5
4	85.5	83.3	80.9	81.5	81.5	84.3	85.5	80.1	82.7	82.7	82.5	82.0	82.7	82.7	82.5	82.5	82.0	82.0
5	85.6	81.6	77.7	81.6	81.6	84.4	82.7	82.7	82.7	82.7	82.5	82.0	82.7	82.7	82.5	82.5	82.0	82.0
6	82.3	83.4	84.0	84.0	84.1	87.3	85.4	85.4	85.4	85.4	80.7	80.1	85.4	85.4	80.7	80.7	80.1	80.1
7	83.3	83.9	83.6	86.1	86.1	86.4	81.4	81.4	81.4	81.3	81.0	80.5	81.3	81.3	81.0	81.0	80.5	80.5
8	81.8	79.7	83.3	84.5	84.5	87.1	87.9	83.3	83.3	83.3	83.0	80.5	83.3	83.3	83.0	83.0	80.5	80.5
9	84.0	80.1	81.3	87.2	88.0	88.0	84.6	80.2	85.8	85.8	75.0	84.1	80.2	85.8	75.0	75.0	84.1	84.1
10	84.7	81.2	85.9	84.9	87.0	86.6	83.4	85.0	85.0	85.0	77.9	80.4	85.0	85.0	77.9	77.9	80.4	80.4
11	83.0	83.6	83.7	87.7	86.6	86.6	84.1	83.5	83.5	83.5	78.9	80.4	83.5	83.5	78.9	78.9	80.4	80.4
12	84.1	82.6	84.0	88.0	86.6	86.6	84.1	83.5	83.5	83.5	78.9	80.4	83.5	83.5	78.9	78.9	80.4	80.4
Average	84.3	82.2	82.4	84.5	86.0	86.0	84.3	82.7	84.3	82.7	79.4	82.1	82.7	82.7	79.4	79.4	82.1	82.1
St. Dev.	1.2	1.5	2.7	2.7	2.3	1.3	2.3	1.9	2.3	1.9	2.4	1.8	2.3	1.9	2.4	2.4	1.8	1.8
RSD	2.0	1.8	3.2	3.2	2.8	1.5	2.8	2.3	2.8	2.3	3.0	2.2	2.3	2.3	3.0	3.0	2.2	2.2

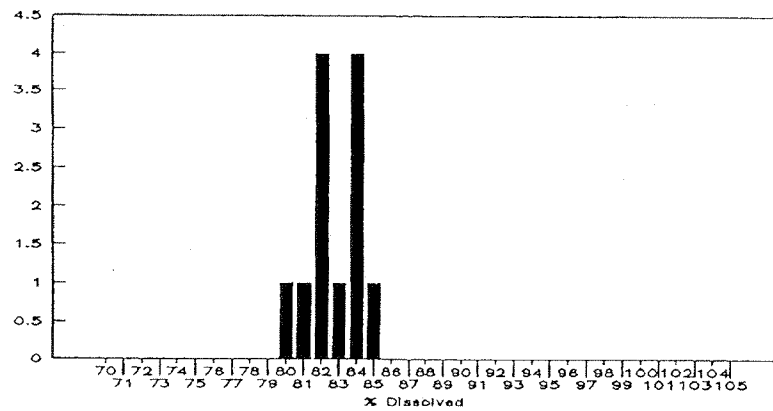
Compression - Dissolution (%) - 60 min.

Batch #	4318A			4318A			4320A			4320A			4322A			4322A		
Sample	1st	Thrd	2nd	Thrd	Final	Thrd	1st	Thrd	2nd	Thrd	Final	Thrd	1st	Thrd	2nd	Thrd	Final	Thrd
1	93.7	95.3	96.2	99.1	104.3	94.4	95.6	94.7	95.6	94.7	94.6	92.3	94.7	94.7	94.6	94.6	92.3	92.3
2	97.2	96.2	95.0	97.0	104.9	96.3	100.4	96.4	100.4	96.4	94.5	97.4	96.4	96.4	94.5	94.5	97.4	97.4
3	98.3	95.0	95.0	97.0	104.9	97.9	100.3	96.4	100.3	96.4	94.5	95.3	96.4	96.4	94.5	94.5	95.3	95.3
4	99.4	99.5	99.5	94.8	106.9	99.2	101.1	100.1	101.1	100.1	93.3	103.6	101.1	100.1	93.3	93.3	103.6	103.6
5	96.7	97.9	95.6	95.1	101.0	100.7	101.8	101.8	101.8	101.8	97.5	100.4	101.8	101.8	97.5	97.5	100.4	100.4
6	97.4	99.5	99.5	95.1	101.0	98.7	93.5	99.1	93.5	99.1	92.7	96.9	93.5	99.1	92.7	92.7	96.9	96.9
7	96.5	95.9	98.3	98.3	99.9	96.7	102.7	101.2	102.7	101.2	96.2	102.5	101.2	101.2	96.2	96.2	102.5	102.5
8	98.5	96.2	94.7	94.7	99.5	102.6	104.4	96.3	104.4	96.3	97.1	97.1	96.3	96.3	97.1	97.1	97.1	97.1
9	97.8	95.3	93.4	93.4	102.2	100.9	99.8	98.0	99.8	98.0	97.1	96.1	98.0	98.0	97.1	97.1	96.1	96.1
10	95.4	101.7	95.4	95.4	98.9	100.5	97.7	103.0	97.7	103.0	93.5	99.2	103.0	103.0	93.5	93.5	99.2	99.2
11	98.0	101.2	96.6	96.6	97.9	98.5	97.7	100.5	98.5	97.7	94.0	99.6	100.5	100.5	94.0	94.0	99.6	99.6
12	100.6	102.2	99.6	99.6	97.4	100.5	99.1	97.6	99.1	97.6	91.7	97.0	97.6	97.6	91.7	91.7	97.0	97.0
Average	97.5	98.0	96.1	96.1	100.5	98.9	98.5	98.6	98.5	98.6	94.9	98.1	98.6	98.6	94.9	94.9	98.1	98.1
St. Dev.	1.8	2.7	2.1	2.1	4.1	2.3	3.0	2.8	3.0	2.8	2.0	3.1	2.8	2.8	2.0	2.0	3.1	3.1
RSD	1.9	2.8	2.2	2.2	4.0	2.3	3.1	2.8	3.1	2.8	2.1	3.2	2.8	2.8	2.1	2.1	3.2	3.2

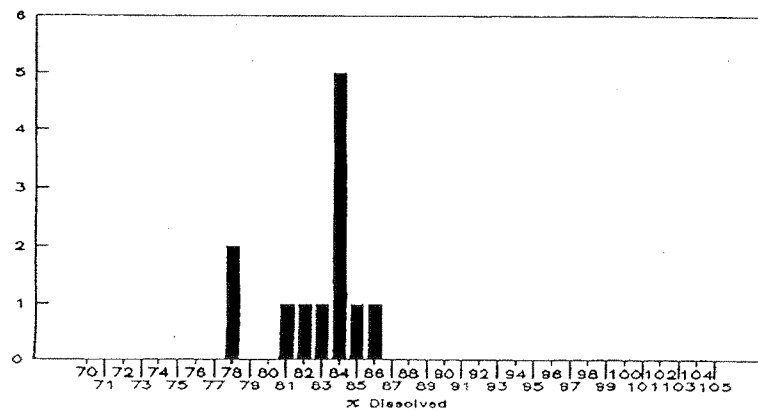
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — 1st Third



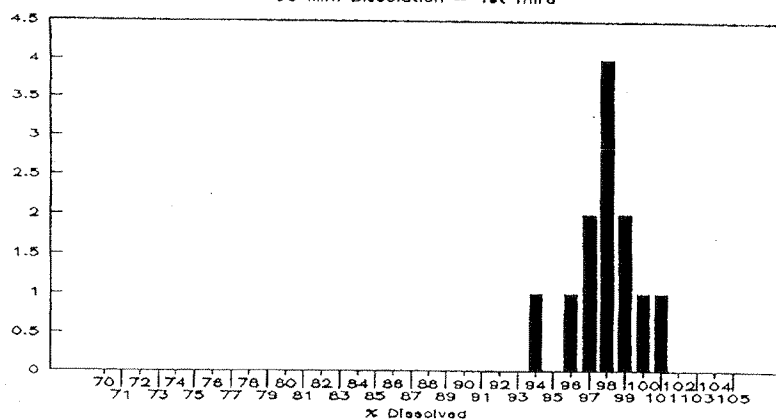
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — 2nd Third



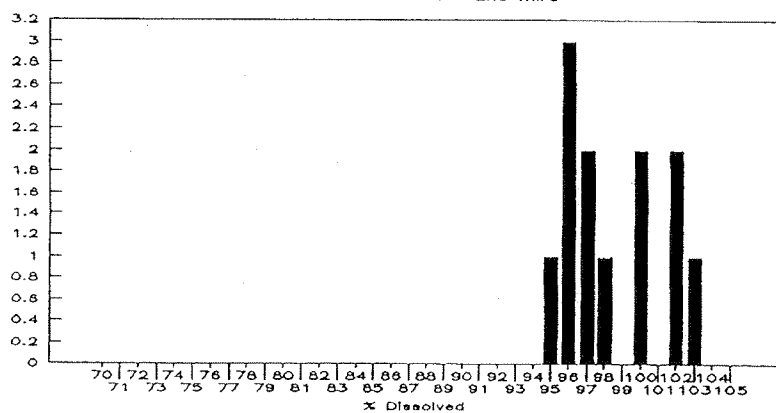
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — Final Third



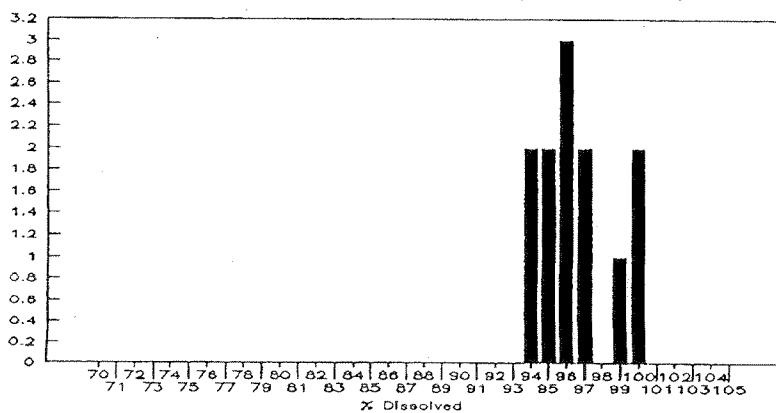
DIGOXIN TABLETS, 0.125 mg — Batch 4318A
60 Min. Dissolution — 1st Third



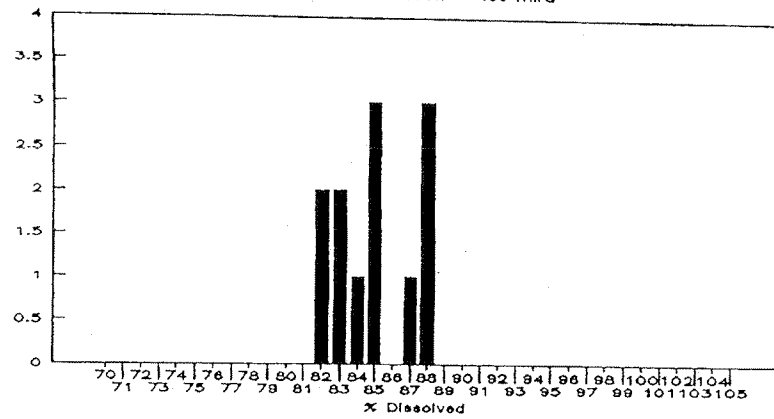
DIGOXIN TABLETS, 0.125 mg — Batch 4318A
60 Min. Dissolution — 2nd Third



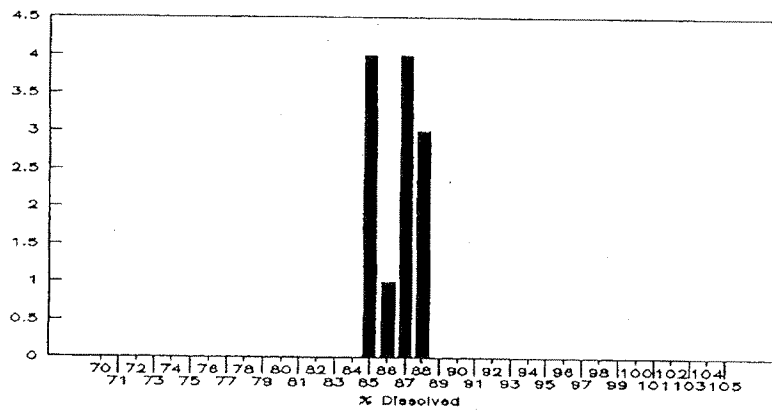
DIGOXIN TABLETS, 0.125 mg — Batch 4318A
60 Min. Dissolution — Final Third



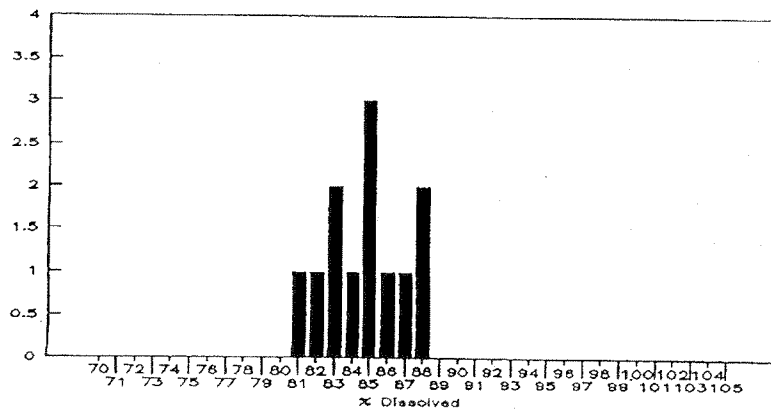
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — 1st Third



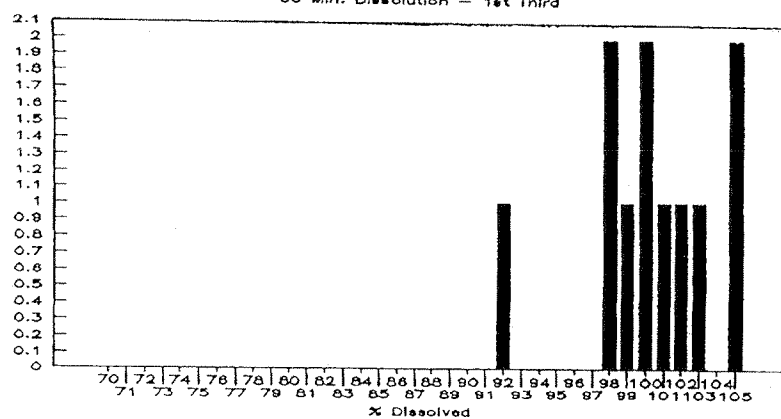
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — 2nd Third



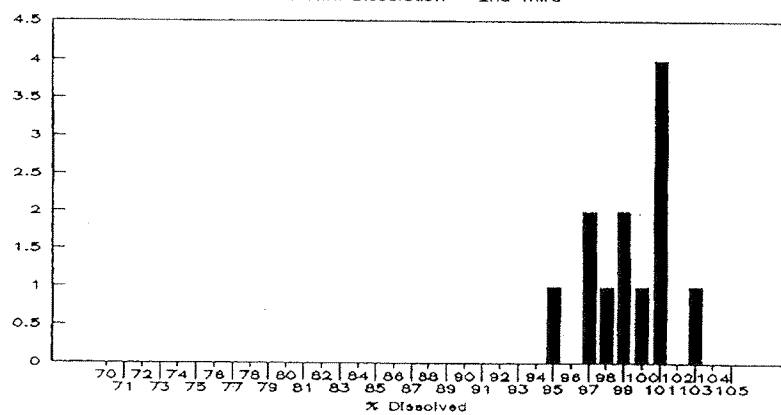
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — Final Third



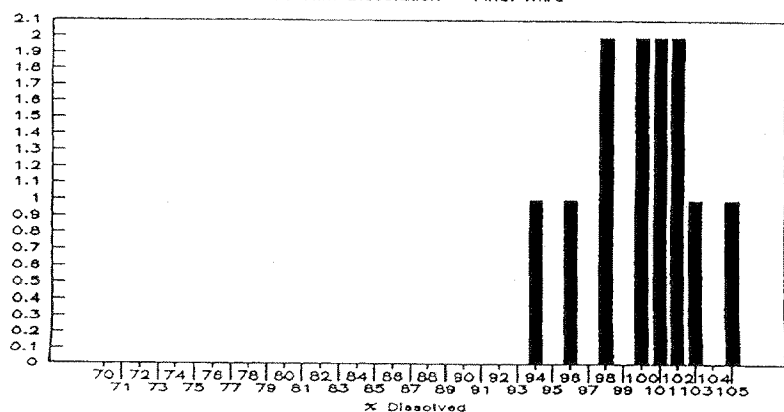
DIGOXIN TABLETS, 0.125 mg — Batch 4320A
60 Min. Dissolution — 1st Third



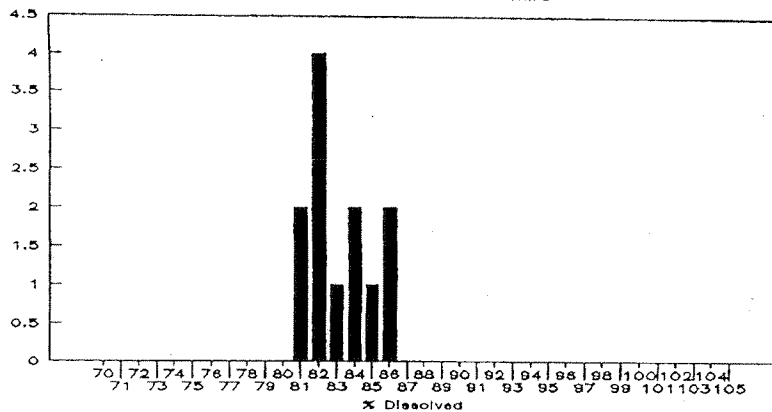
DIGOXIN TABLETS, 0.125 mg — Batch 4320A
60 Min. Dissolution — 2nd Third



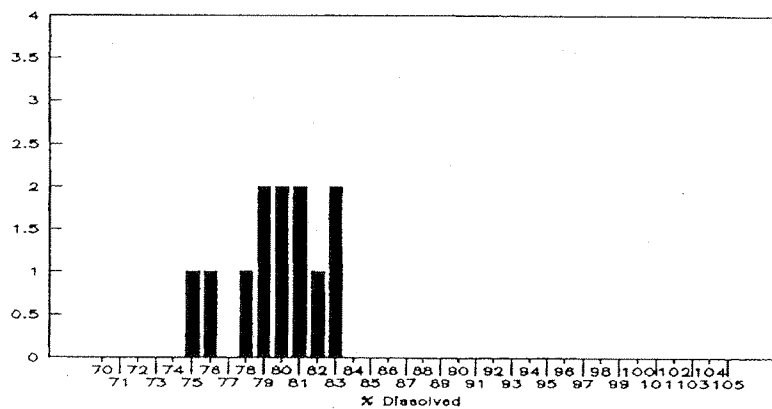
DIGOXIN TABLETS, 0.125 mg — Batch 4320A
60 Min. Dissolution — Final Third



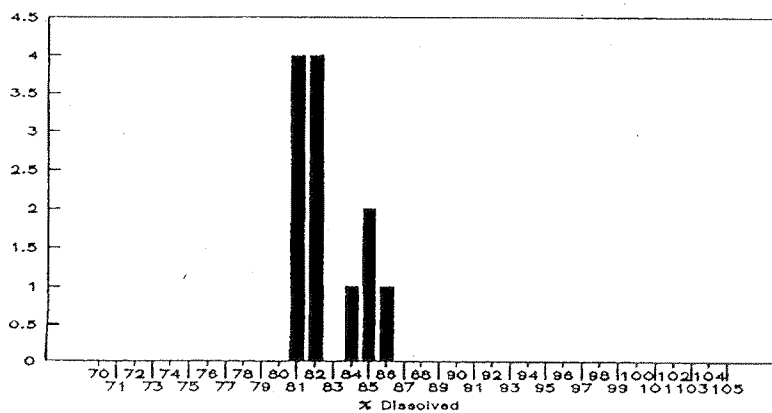
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — 1st Third



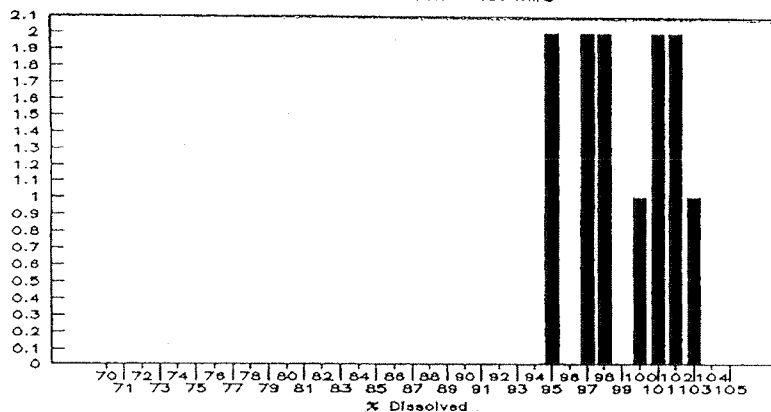
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — 2nd Third



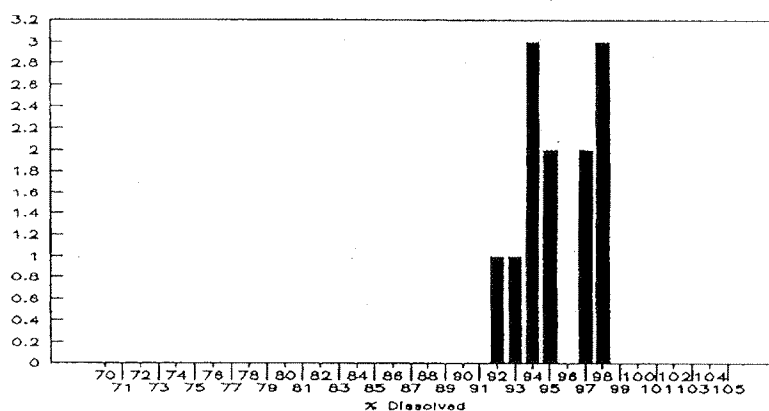
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — Final Third



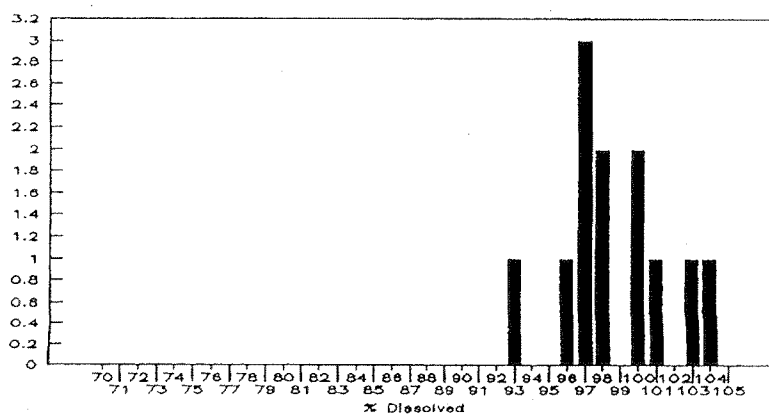
DIGOXIN TABLETS, 0.125 mg — Batch 4322A
60 Min. Dissolution — 1st Third



DIGOXIN TABLETS, 0.125 mg — Batch 4322A
60 Min. Dissolution — 2nd Third



DIGOXIN TABLETS, 0.125 mg — Batch 4322A
60 Min. Dissolution — Final Third

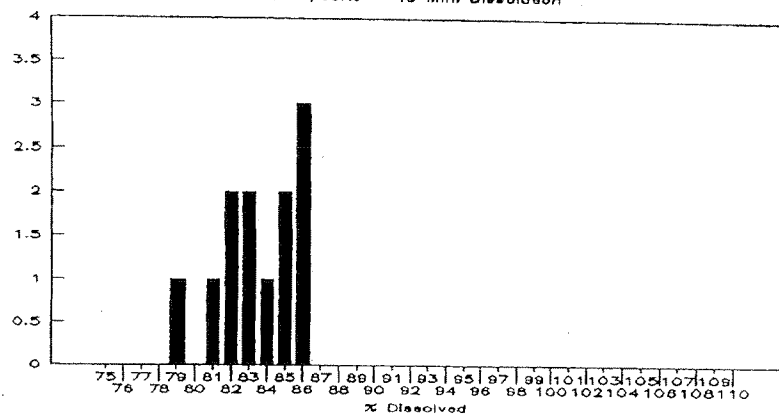


AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

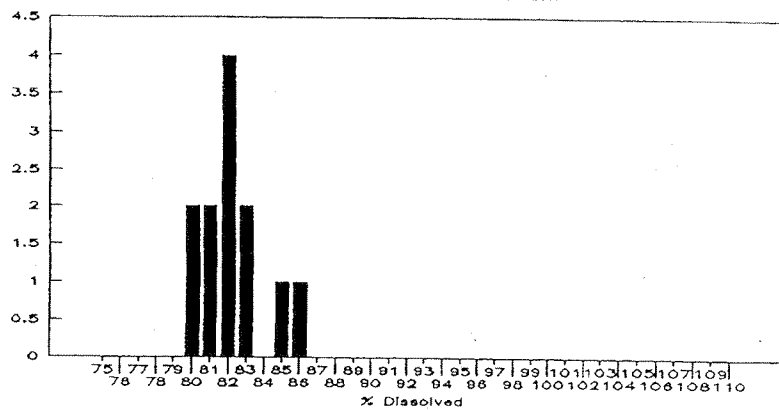
Compression - Composite Dissolution (%)

Batch #	4318A	4318A	4320A	4320A	4322A	4322A
Time	15 min.	60 min.	15 min.	60 min.	15 min.	60 min.
1	85.8	100.3	81.0	99.1	78.4	97.4
2	83.0	100.0	81.9	98.7	79.9	98.9
3	80.6	97.2	82.1	98.3	78.9	95.2
4	83.1	96.6	81.7	99.1	77.7	95.8
5	85.3	101.3	82.3	98.4	79.0	94.8
6	81.7	99.9	81.8	95.9	77.9	96.0
7	85.6	99.4	80.8	100.5	84.3	98.2
8	81.9	95.1	80.0	98.2	83.9	98.4
9	82.5	97.9	79.5	98.4	80.3	95.0
10	85.0	98.4	85.6	101.8	82.5	95.9
11	84.6	100.6	81.5	96.5	81.4	99.2
12	78.1	99.6	84.6	99.5	81.0	93.6
Average	83.1	98.9	81.9	98.7	80.4	96.5
St. Dev.	2.3	1.8	1.7	1.6	2.2	1.8
RSD	2.8	1.9	2.1	1.6	2.8	1.9

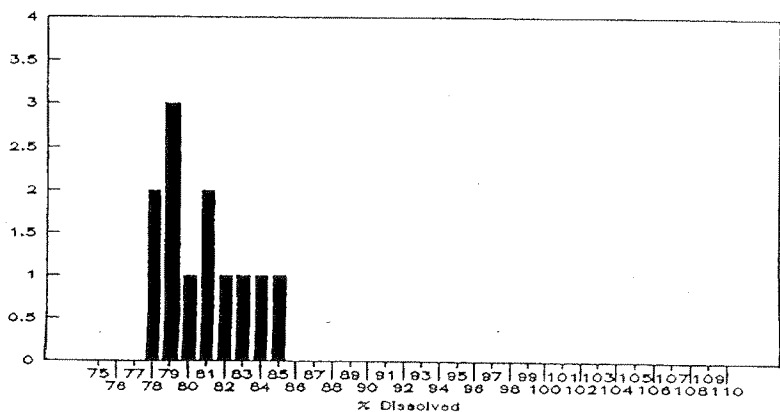
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
Composite — 10 Min. Dissolution



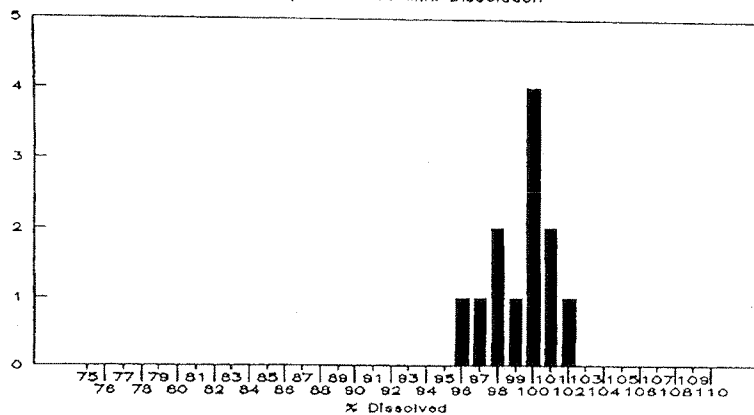
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
Composite — 15 Min. Dissolution



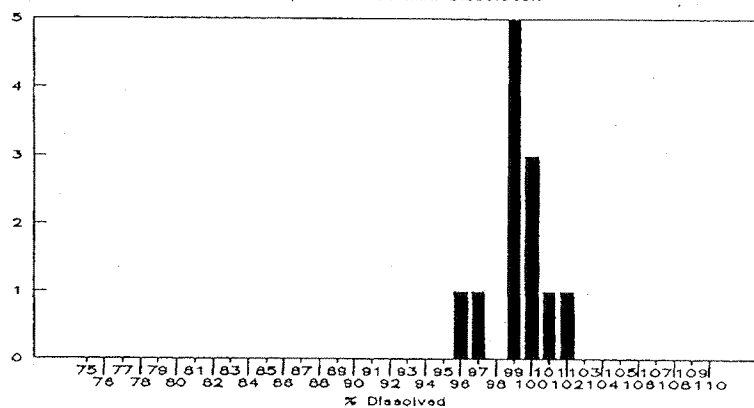
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
Composite — 15 Min. Dissolution



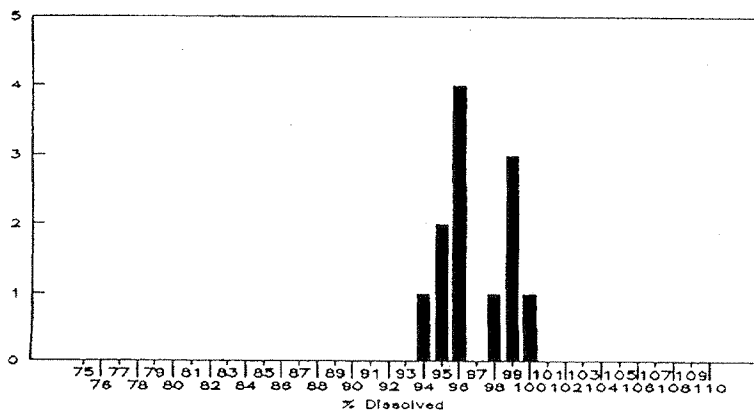
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
Composite — 60 Min. Dissolution



DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
Composite — 60 Min. Dissolution



DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
Composite — 60 Min. Dissolution



AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg

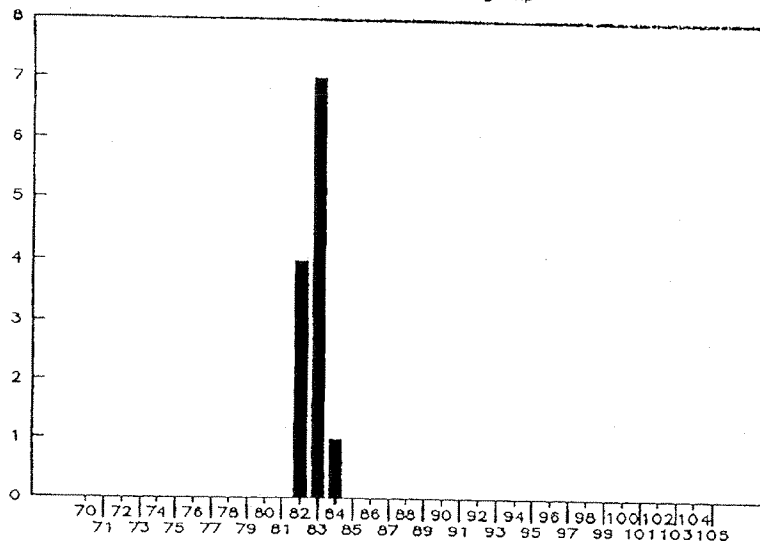
High/Low kp - Dissolution (%) - 15 min.

Batch #	4318A	4318A	4318A	4318A	4318A	4320A	4320A	4320A	4320A	4320A	4322A	4322A	4322A	4322A
Sample Side	High kp	High kp	Low kp	Low kp	Low kp	High kp	High kp	Low kp	Low kp	Low kp	High kp	High kp	Low kp	Low kp
	Front	Rear	Front	Rear	Front	Front	Rear	Front	Rear	Front	Front	Rear	Front	Rear
1	81.2	82.0	81.3	81.7	81.5	83.5	83.5	83.3	81.4	81.4	69.8	83.7	83.3	76.8
2	81.4	82.6	80.8	85.9	82.9	87.2	87.2	83.5	82.5	82.5	83.2	79.9	82.2	83.4
3	82.6	82.9	82.0	83.7	84.8	87.2	87.2	80.9	83.0	83.0	76.9	82.7	83.2	85.5
4	82.1	82.1	81.7	83.2	83.0	86.9	86.9	81.1	81.7	81.7	83.6	83.1	84.6	83.9
5	82.8	82.3	81.6	82.7	84.0	87.9	87.9	85.4	84.6	84.6	81.3	84.7	82.2	84.8
6	81.8	83.7	81.9	82.8	83.1	86.7	86.7	81.2	83.9	83.9	72.6	77.3	82.3	84.1
Average	82.0	82.6	81.6	83.3	83.2	86.6	86.6	82.6	82.9	82.9	77.9	81.9	83.0	83.1
St. Dev.	0.6	0.6	0.4	1.4	1.1	1.6	1.6	1.8	1.2	1.2	5.8	2.8	0.9	3.2
RSD	0.8	0.8	0.5	1.7	1.3	1.8	1.8	2.2	1.5	1.5	7.4	3.4	1.1	3.8

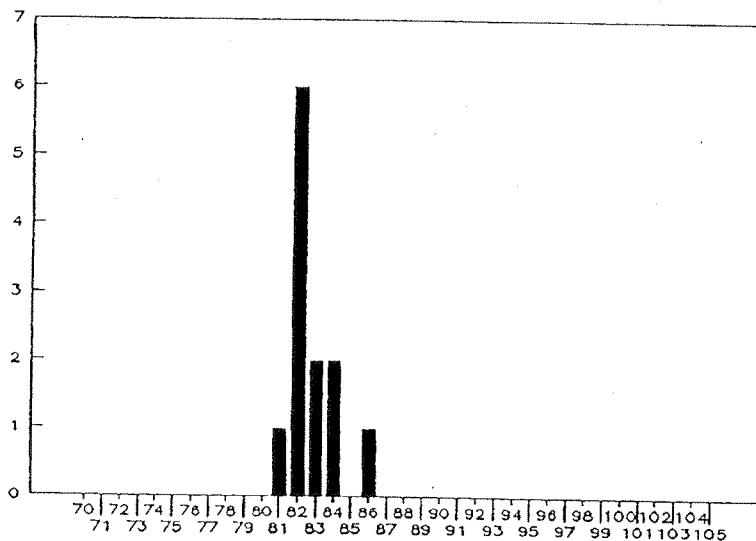
High/Low kp - Dissolution (%) - 60 min.

Batch #	4318A	4318A	4318A	4318A	4318A	4320A	4320A	4320A	4320A	4320A	4322A	4322A	4322A	4322A
Sample Side	High kp	High kp	Low kp	Low kp	Low kp	High kp	High kp	Low kp	Low kp	Low kp	High kp	High kp	Low kp	Low kp
	Front	Rear	Front	Rear	Front	Front	Rear	Front	Rear	Front	Front	Rear	Front	Rear
1	98.5	100.0	102.8	98.6	100.7	99.0	99.0	95.7	97.7	97.7	97.2	102.5	91.7	94.1
2	97.4	101.6	99.0	98.4	103.6	99.6	99.6	96.7	97.8	97.8	96.4	99.8	94.0	95.6
3	97.9	100.9	98.6	98.0	104.5	99.8	99.8	95.7	96.9	96.9	99.7	98.0	96.2	98.5
4	97.7	96.8	98.4	102.2	99.2	99.3	99.3	96.1	94.6	94.6	95.5	94.7	94.5	95.7
5	95.8	95.1	99.6	98.8	99.5	101.5	101.5	99.7	97.2	97.2	100.4	98.0	91.8	97.8
6	99.1	95.4	99.1	100.7	98.9	98.0	98.0	97.2	95.7	95.7	94.5	96.8	94.4	95.2
Average	97.7	98.3	99.6	99.5	101.1	99.7	99.7	96.9	96.7	96.7	97.3	98.3	93.8	96.2
St. Dev.	1.1	2.9	1.6	1.6	2.4	0.9	0.9	1.5	1.3	1.3	2.3	2.7	1.7	1.7
RSD	1.2	2.9	1.6	1.7	2.4	0.9	0.9	1.6	1.3	1.3	2.4	2.7	1.9	1.7

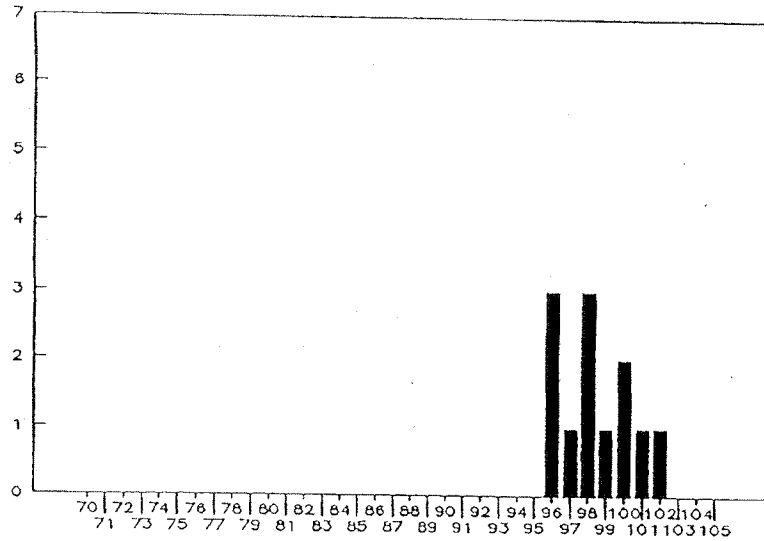
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — High kp



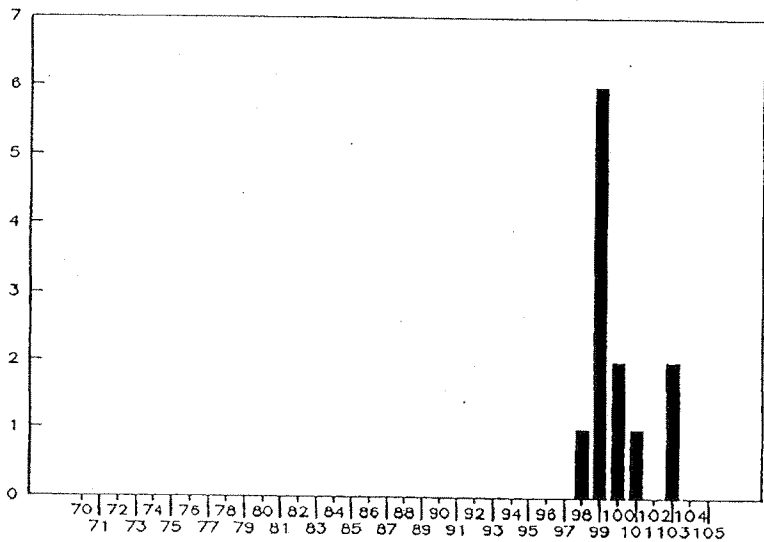
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
15 Min. Dissolution — Low kp



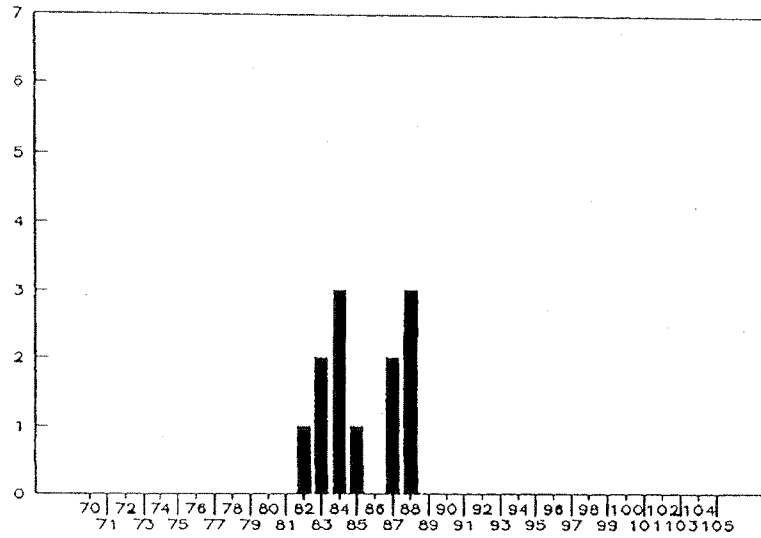
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
60 Min. Dissolution — High kp



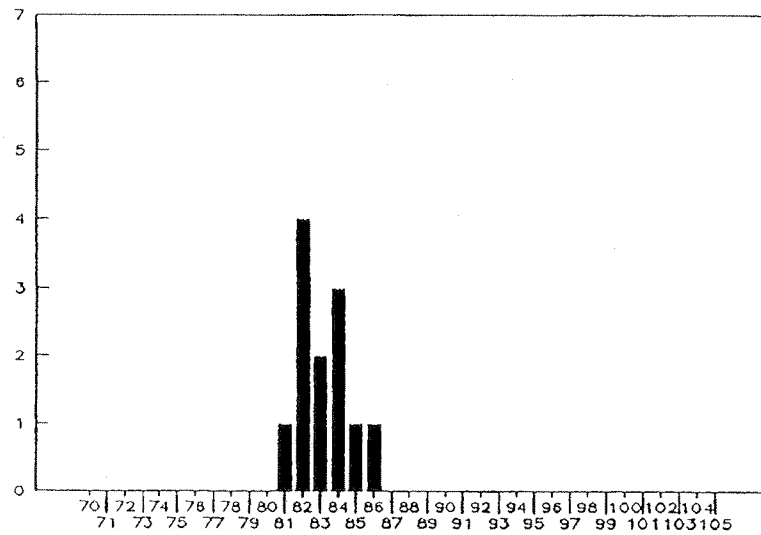
DIGOXIN TABLETS, 0.125 mg — BATCH 4318A
60 Min. Dissolution — Low kp



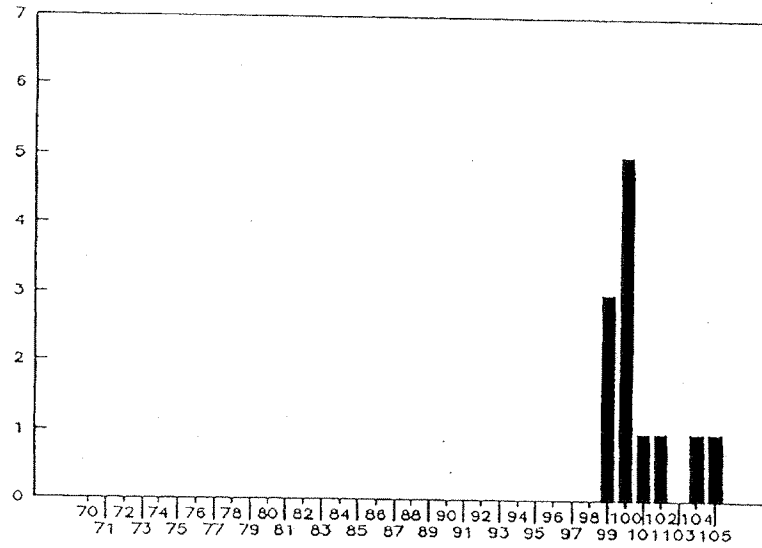
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — High kp



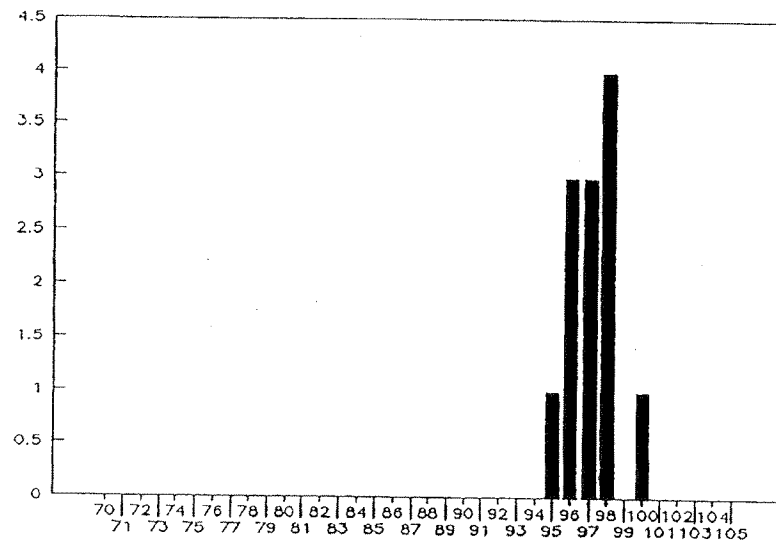
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
15 Min. Dissolution — Low kp



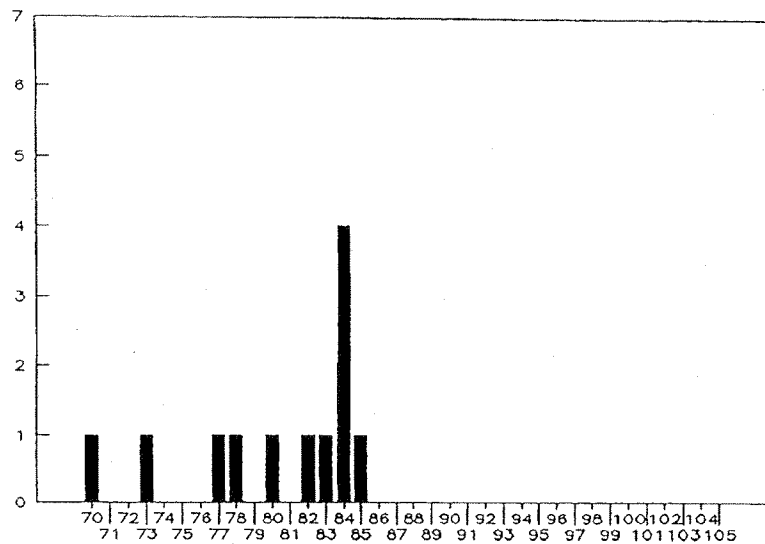
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
60 Min. Dissolution — High kp



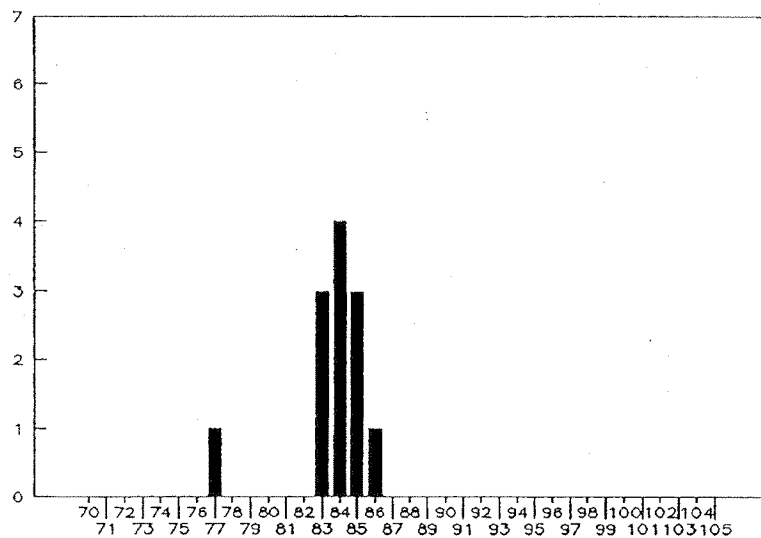
DIGOXIN TABLETS, 0.125 mg — BATCH 4320A
60 Min. Dissolution — Low kp



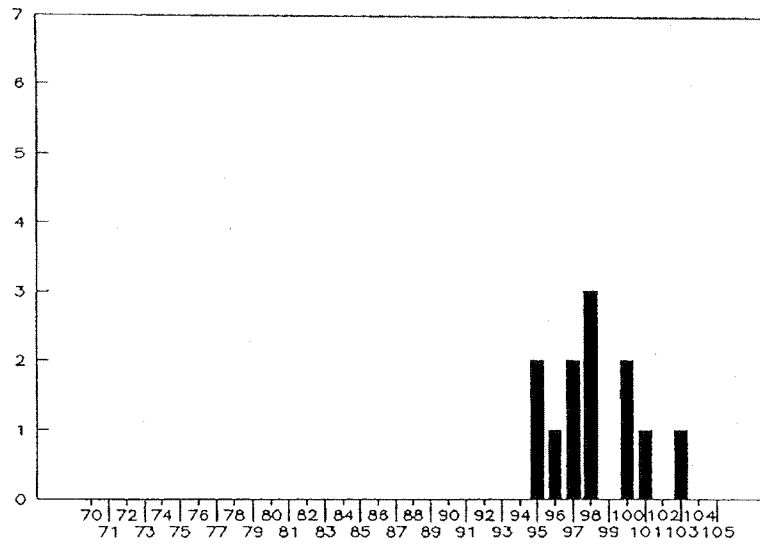
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — High kp



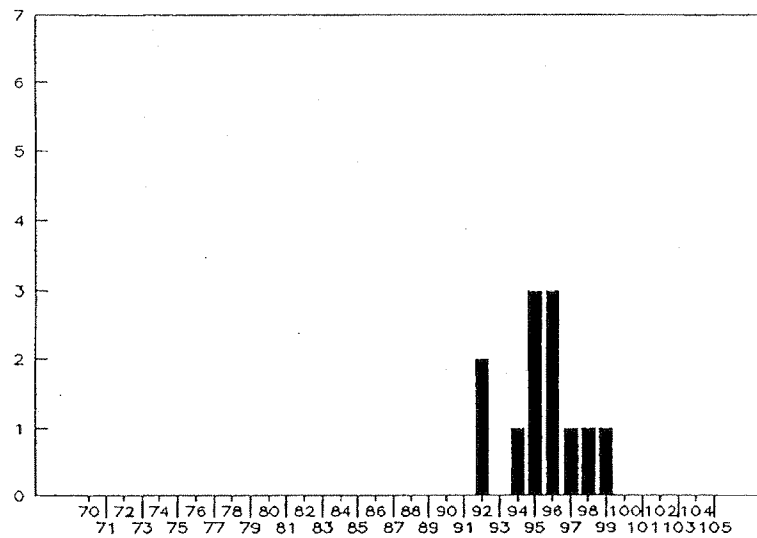
DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
15 Min. Dissolution — Low kp



DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
60 Min. Dissolution — High kp



DIGOXIN TABLETS, 0.125 mg — BATCH 4322A
60 Min. Dissolution — Low kp



Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125 mg (145)BATCH #: 4322ATABLET PRESS ID #: 66

	Limit	Time
High KP	above 6 kp	5.46 pm
Low KP	0.5 - 2.0 kp	5.58 pm
Maximum KP	Not Possible	—
Regular Speed	21 RPM	—

	RPM	Time
High Speed	26	6.10 pm
Low Speed	14	6.23 pm

Done By: <u>K-P</u>	Date: <u>11/17/94</u>
---------------------	-----------------------

P0301.1

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mgBatch #: 4322ADate: 11/18/14Tablet Press Id: 66Hardness Tester Id: 251Thickness Gauge Id: 646Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP 125P 11/11/14

High KP — Above 6.0 KP RDM-21

Front Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
5.45 Pm 1 Min.	1.064	2.60 2.59 2.60	5.8 4.9 5.5	1.0 1.0
5.49 Pm 5 Min.	1.066	2.56 2.55 2.58 4.9	5.5 5.2	1.0 1.0

Rear Exit Chute								
Time	Weight* (g)	Thickness mm	Hardness KP	Init				
1 Min.	1.046	2.54	2.57	5.8	5.4	5.6	1.0	
5 Min.	1.051	2.51	2.62	2.56	5.1	5.3	6.1	1.0

* Composite Weight of 10 Tablets

Front Exit Chute									
Time	Weight of Each Tablet (mg)								
1 Min.	104	104	107	108	104	107	105	105	108
5 Min.	106	106	105	106	104	109	100	108	104

Rear Exit Chute									
Time	Weight of Each Tablet (mg)								
1 Min.	106	107	103	108	105	104	104	109	105
5 Min.	107	106	103	103	104	103	104	108	107

Comments:

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: **145** Prod Name: **Digoxin Tablets 0.125 mg**Batch #: **4322A**Date: **11/18/14**Tablet Press Id: **66**Hardness Tester Id: **251**Thickness Gauge Id: **646**Scale Id: **235**

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm

Hardness Limits

: ~~1.0 - 6.0 KP~~ **1.0 - 6.0 KP** 11/11/14*done KP* **0.5 - 2.0 KP** **RPM-21**

Front Exit Chute					
Time	Weight* (g)	Thickness mm	Hardness KP		Init
5-57 min	1.061	3.10	3.66	0.9	1.0
1 Min.					K.D
5 Min.	1.056	3.09	3.10	1.0	0.9
				1.2	K.D

Rear Exit Chute					
Time	Weight* (g)	Thickness mm	Hardness KP		Init
1 Min.	1.047	3.12	3.09	3.08	0.9
				1.1	1.2
5 Min.	1.053	3.05	3.04	3.06	1.2
				0.8	K.D

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	107	104	102	106	104	106	106	107	108	104
5 Min.	103	107	107	108	106	106	105	105	107	106

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	103	106	104	108	104	106	103	102	103	110
5 Min.	109	103	102	102	105	108	104	105	106	106

Comments:

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1COMPRESSION DATA SHEETProd Id: 145 Prod Name: Digoxin Tablets 0.125 mgBatch #: 4322ADate: 11/18/04Tablet Press Id: C6Hardness Tester Id: 251Thickness Gauge Id: C46Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed - 26 RPM

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP		Init	
1 min. 1 min.	1.000	2.50	2.52	2.53	2.5	2.6	2.7	1.0
6-13 5 min.	0.986	2.52	2.59	2.51	3.1	2.3	2.9	1.0

Rear Exit Chute								
Time	Weight* (g)	Thickness mm		Hardness KP		Init		
1 Min.	0.979	2.61	2.52	2.52	3.4	3.2	3.6	KD
5 Min.	1.001	2.51	2.57	2.50	2.8	3.8	3.1	1.0

* Composite Weight of 10 Tablets

Front Exit Chute									
Time	Weight of Each Tablet(mg)								
1 Min.	95	93	95	100	98	98	100	99	99
5 Min.	105	106	96	101	99	94	99	98	100

Rear Exit Chute									
Time	Weight of Each Tablet(mg)								
1 Min.	101	102	99	105	98	96	98	100	99
5 Min.	102	99	93	99	99	97	100	101	99

Comments:

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mgBatch #: 4322ADate: 11/18/94Tablet Press Id: 66 Hardness Tester Id: 251Thickness Gauge Id: CU6 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

slow Speed - 14 RPM

Front Exit Chute								
Time	Weight* (g)	Thickness mm			Hardness KP	Init		
0.25 min	1.050	2.62	2.64	2.65	4.3	5.2	4.4	K.D
1 Min.								
5-26 min	1.058	2.66	2.65	2.64	4.7	4.5	4.1	K.D
5 Min.								

Rear Exit Chute								
Time	Weight* (g)	Thickness mm		Hardness KP		Init		
1 Min.	1.069	2.63	2.61	2.60	5.0	4.1	4.5	1.0
5 Min.	1.082	2.62	2.71	2.63	4.5	4.9	6.2	1.0

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 min.	105	107	106	104	103	107	105	104	108	105
5 min.	103	106	106	104	106	104	104	105	106	105

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	110	105	106	109	106	106	107	108	104	108
5 Min.	108	107	109	106	110	111	106	110	108	109

Comments:

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125 Mg (145)BATCH #: 4318 ATABLET PRESS ID #: 66

	Limit	Time
High KP	above 6 KP	11.45 AM
Low KP	0.5 - 2.0 KP	12.18 PM
Maximum KP	not possible	—
Regular Speed	21 RPM	—

	RPM	Time
High Speed	26	12.48 PM
Low Speed	14	1.15 PM

Done By: <u>KP</u>	Date: <u>11/14/94</u>
--------------------	-----------------------

FD 301.1

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: **145** Prod Name: **Digoxin Tablets 0.125 mg**Batch #: **4818A**Date: **11/14/94**Tablet Press Id: **66**Hardness Tester Id: **251**Thickness Gauge Id: **646**Scale Id: **235**

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : ~~1.0 - 6.0 KP~~ **11/5/94**

High KP Above 6 RPM - 21

Front Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
1 Min.	1.049	2.56	2.60	2.57
1 Min.	1.048	2.57	2.57	2.56
5 Min.	1.054	2.57	2.57	2.56

Rear Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
1 Min.	1.044	2.52	2.53	2.53
1 Min.	1.052	2.55	2.60	2.58
5 Min.	1.052	2.55	2.60	2.58

* Composite Weight of 10 Tablets

Front Exit Chute									
Time	Weight of Each Tablet (mg)								
1 Min.	104	105	104	104	105	105	106	104	106
5 Min.	106	105	105	106	105	105	104	104	104

Rear Exit Chute									
Time	Weight of Each Tablet (mg)								
1 Min.	105	105	107	103	106	106	105	106	106
5 Min.	105	103	105	107	107	109	105	104	106

Comments: Hardness of 6.0 kp and above can not be achieved. Maximum hardness of 5.8 kps was obtained. And 11/14/94

<P0187.1>

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mgBatch #: 4318ADate: 11/14/99Tablet Press Id: 66 Hardness Tester Id: 251Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP 11/3/99

kp 0.5 - 2.0 rpm - 21

Front Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
12.15 min	1.049	3.12	3.09	3.08
1 Min.			1.0	0.9
1.019 min	1.075	3.14	3.12	3.10
5 Min.			0.9	1.0
			1.6	1.6
				KP

Rear Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
1 Min.	1.044	2.98	2.97	2.99
1.019 min	1.054	3.06	2.99	2.99
5 Min.			1.9	1.5
			1.7	1.7
				KP

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	103	104	105	104	105	106	106	104	105	105
5 Min.	104	110	109	105	110	105	112	112	110	105

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	107	102	103	103	105	103	104	102	102	106
5 Min.	103	104	106	107	106	104	104	107	104	105

Comments:

KPO187.13

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4318A

Date: 11/14/94

Tablet Press Id: 65

Hardness Tester Id: 251

Thickness Gauge Id: 646

Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed 26 RPM

Front Exit Chute					
Time	Weight* (g)	Thickness mm	Hardness KP	Init	
12:47 PM	1.049	2.63	2.62	4.3	4.1
1 Min.				3.8	4.1
5 Min.	1.066	2.71	2.69	4.5	4.6
				4.6	4.2
					KP

Rear Exit Chute					
Time	Weight* (g)	Thickness mm	Hardness KP	Init	
1 Min.	1.058	2.64	2.58	4.4	4.5
				4.5	4.5
5 Min.	1.056	2.57	2.67	4.0	4.6
				5.2	KP

* Composite Weight of 10 Tablets

Front Exit Chute									
Time	Weight of Each Tablet(mg)								
12:47 PM	105	101	109	107	101	110	106	102	105
1 Min.									109
5 Min.	105	103	105	102	106	103	106	107	100
									104

Rear Exit Chute									
Time	Weight of Each Tablet(mg)								
1 Min.	105	109	110	106	110	105	106	107	104
									102
5 Min.	102	110	107	104	102	103	106	110	103

Comments:

P0187.12

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1COMPRESSION DATA SHEETProd Id: 145 Prod Name: Digoxin Tablets 0.125 mgBatch #: 4318ADate: 11/14/94Tablet Press Id: 66Hardness Tester Id: 251Thickness Gauge Id: 64CScale Id: 835

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

low speed 14 RPM

Front Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
1 Min.	1.054	2.62	2.62	4.4
1 Min.	1.054	2.62	2.64	4.2
1 Min.	1.054	2.62	2.64	4.7
5 Min.	1.057	2.62	2.64	4.5
			5.2	4.4
			4.4	4.9
				KP

Rear Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
1 Min.	1.063	2.67	2.64	5.0
1 Min.	1.063	2.67	2.64	4.5
1 Min.	1.063	2.67	2.65	4.4
5 Min.	1.069	2.67	2.65	4.4
			4.0	5.2
				KP

* Composite Weight of 10 Tablets

Front Exit Chute									
Time	Weight of Each Tablet(mg)								
1 Min.	106	102	105	106	105	104	106	108	105
5 Min.	106	105	108	103	107	107	104	105	107

Rear Exit Chute									
Time	Weight of Each Tablet(mg)								
1 Min.	107	107	107	106	105	106	105	104	105
5 Min.	105	105	107	106	109	107	106	107	105

Comments:

4

Amide Pharmaceutical, Inc.

COMPRESSION DEPARTMENT

PROCESS VALIDATION

PRODUCT NAME: Digoxin Tablets 0.125 mg (145)BATCH #: 4320 ATABLET PRESS ID #: 66

	Limit	Time
High KP	above 6 KP	2.50 Pm
Low KP	0.5 - 2.0 KP	3.20 Pm
Maximum KP	Not Possible	—
Regular Speed	21 RPM	—

	RPM	Time
High Speed	26	3.50 Pm
Low Speed	14	4.20 Pm

Done By:	JCP	Date:	11/15/94
----------	-----	-------	----------

PB301.1

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4320A Date: 11/15/94Tablet Press Id: SC Hardness Tester Id: 251Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : ~~1.0 - 6.0 KP~~ 2.0 - 2.5 KP 11/9/94

for KP — 0.5 - 2.0 KP 2.0 - 2.1

Front Exit Chute								
Time	Weight* (g)	Thickness mm	Hardness KP		Init			
1 Min.	1.0558	3.3	3.1	3.6	1.2	1.3	1.2	2.1
5 Min.	1.0664	3.2	3.3	2.97	1.4	1.2	1.4	KP

Rear Exit Chute								
Time	Weight* (g)	Thickness mm		Hardness KP		Init		
1 min.	1.0555	3.6	2.98	3.6	1-3	2.0	1.6	KP
5 min.	1.053	2.98	3.68	2.98	1-1	1-7	1-5	KP

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	105	103	105	112	105	104	107	105	104	102
5 Min.	108	105	106	103	110	105	107	105	113	103

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	102	103	104	105	106	105	104	105	106	106
5 Min.	106	105	107	104	107	104	105	105	105	106

Comments:

<P0187.1>

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4320A Date: 11/15/94

Tablet Press Id: 66 Hardness Tester Id: 251Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

High Speed - 26 RPM

Front Exit Chute						
Time	Weight* (g)	Thickness mm	Hardness KP	Init		
3-4 g pieces 1 min.	1.013	2.53	2.55	2.53	4.5	3-0
5-55 gms 5 min.	1.000	2.55	2.57	2.53	4.4	3.5
					2.2	KP

Rear Exit Chute					
Time	Weight* (g)	Thickness mm	Hardness KP	Init	
1 Min.	1.010	2.54 2.60	2.61 4.2	4.6 3.0	KP
5 Min.	1.009	2.62 2.53	2.59 3.2	4.4 3.7	KP

* Composite Weight of 10 Tablets

Front Exit Chute										
Time	Weight of Each Tablet(mg)									
1 min.	100	99.4	99.5	107	104	99.8	100	99.9	103	103
5 min.	106	107	107	99.5	100	100	102	102	101	99.4

Rear Exit Chute										
Time	Weight of Each Tablet(mg)									
1 Min.	100	99.9	99.8	100	99.8	104	104	104	104	99.8
5 Min.	99.9	99.4	104	99.7	99.4	104	106	105	99.8	103

Comments:

P0187.13

Amide Pharmaceutical, Inc.

Process Validation

Page 1 of 1

COMPRESSION DATA SHEET

Prod Id: 145 Prod Name: Digoxin Tablets 0.125 mg

Batch #: 4320A

Date: 11/15/94

Tablet Press Id: 66 Hardness Tester Id: 251

Thickness Gauge Id: 646 Scale Id: 235

Target Weight (1 Tablet) : 105.0 mg
 Target Weight (10 Tablets) : 1.050 g
 Weight Range (10 Tablets) : 1.019 - 1.082 g

Thickness Limits : 2.0 - 3.0 mm
 Hardness Limits : 1.0 - 6.0 KP

slow speed 14 RPM

Front Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
1 Min.	1.054	2.65	2.63	5.0
5 Min.	1.058	2.65	2.64	4.6

Rear Exit Chute				
Time	Weight* (g)	Thickness mm	Hardness KP	Init
1 Min.	1.047	2.66	2.60	4.4
5 Min.	1.062	2.67	2.64	4.3

* Composite Weight of 10 Tablets

Front Exit Chute									
Time	Weight of Each Tablet(mg)								
1 Min.	104	104	106	108	104	106	111	109	108
5 Min.	105	105	106	106	107	107	104	105	104

Rear Exit Chute									
Time	Weight of Each Tablet(mg)								
1 Min.	103	107	101	107	103	104	104	106	106
5 Min.	105	104	106	102	105	104	107	106	106

Comments:

<P0187.1>

Amide Pharmaceutical, Inc.

Page 1 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets 0.125 mg

SPECIFICATION: USP

CONTROL #: 4318A

CHEMIST: S.J/PK VOLUME #: 318 02/21/04 PAGE #: 27/211 DATE: 11/17/94

SAMPLE STAGE: Overall Composite Bid: 11/16/94

TEST	RESULT	LIMIT
DESCRIPTION: Color:	Yellow	Yellow
Profile:	Round Bisected Tablets	Round Bisected Tablets
Other: Debossed	"A 145" on bisected side of the tablet	"A 145" on bisected side of the tablet
THICKNESS: (Guideline)	2.6 mm	2.0 mm to 3.0 mm
WEIGHT VARIATION:	105.3 mg	± 10% Theo. wt (105 mg) 94.5 mg - 115.5 mg
RIABILITY:	0.02 %	NMT 1.0 %
IDENTIFICATION: (A)	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.
ASSAY: Digoxin, 0.125 mg	100.0 %	90.0% to 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity)	1) 102.3 % 6) 101.6 % 2) 104.6 % 7) 100.4 % 3) 103.9 % 8) 101.6 % 4) 101.5 % 9) 100.7 % 5) 99.9 % 10) 101.7 % AV: 101.7 % RSD: 1.5 %	85.0% to 115.0%
(✓) COMPLIES	PREPARED BY: Philena Patel	DATE: 11/17/94
() DOES NOT COMPLY	APPROVED BY: Suzanne Patel	DATE: 11/17/94

0013-145c

Pharmaceutical, Inc.

Page 2 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USPCONTROL #: 4318ACHEMIST: S.J/P.K.
H.D.VOLUME #: 918.00/321-0
330.00PAGE #: 27/211
200DATE: 11/17/94SAMPLE STAGE: Overall Composite Dist. 11/16/94

TEST	RESULT	LIMIT
DISSOLUTION: Media: 500mL 0.1N HCl Appar: I, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes	15 minutes: 1) <u>95.8</u> % 7) <u>95.6</u> % 2) <u>93.0</u> % 8) <u>91.9</u> % 3) <u>91.6</u> % 9) <u>92.5</u> % 4) <u>93.1</u> % 10) <u>85.0</u> % 5) <u>95.3</u> % 11) <u>94.6</u> % 6) <u>91.7</u> % 12) <u>98.1</u> % Average: <u>93.1</u> % 60 minutes: 1) <u>100.3</u> % 7) <u>99.4</u> % 2) <u>100.0</u> % 8) <u>95.1</u> % 3) <u>97.2</u> % 9) <u>97.9</u> % 4) <u>96.6</u> % 10) <u>98.4</u> % 5) <u>101.3</u> % 11) <u>100.6</u> % 6) <u>99.9</u> % 12) <u>99.6</u> % Average: <u>98.9</u> %	(Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual Tablet. (LC: Labeled amount)
<input checked="" type="checkbox"/> COMPLIES <input type="checkbox"/> DOES NOT COMPLY	PREPARED BY: <u>Milesch Patel</u> DATE: <u>11/17/94</u> APPROVED BY: <u>Suryakant Patel</u> DATE: <u>11/17/94</u>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> APPROVED BY <u>S.D.</u> DATE <u>11/17/94</u> </div>

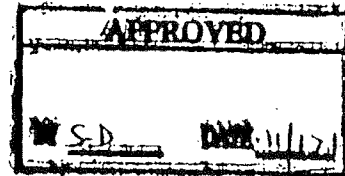
QC13-145d

Amide Pharmaceutical, Inc.

Page 1 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets 0.125 mgSPECIFICATION: USPCONTROL #: 4320ACHEMIST: NP/PKVOLUME #: 30602/321-04 PAGE #: 25/213DATE: 11/17/94SAMPLE STAGE: over all complete dated 11/16/94

TEST	RESULT	LIMIT
DESCRIPTION: Color:	<u>Yellow</u>	Yellow
Profile:	<u>Round bisected Tablets</u>	Round Bisected Tablets
Other: Debossed	<u>"A 145" on bisected side of the tablet</u>	"A 145" on bisected side of the tablet
THICKNESS: (Guideline)	<u>2.6 mm</u>	2.0 mm to 3.0 mm
WEIGHT VARIATION:	<u>104.9 mg.</u>	± 10% Theo. wt (105 mg) 94.5 mg - 115.5 mg
RIABILITY:	<u>0.02 %</u>	NMT 1.0 %
IDENTIFICATION: (A)	<u>The retention time of the major peak in the chromatogram of Assay prep. corresponds to standard prep.</u>	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.
ASSAY: Digoxin, 0.125 mg	<u>100.6 %</u>	90.0% to 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity)	1) <u>99.7 %</u> 6) <u>100.7 %</u> 2) <u>100.2 %</u> 7) <u>99.8 %</u> 3) <u>99.7 %</u> 8) <u>99.9 %</u> 4) <u>100.2 %</u> 9) <u>100.3 %</u> 5) <u>101.2 %</u> 10) <u>102.7 %</u> AV: <u>100.5</u> RSD: <u>0.91</u>	85.0% to 115.0%
(<input checked="" type="checkbox"/>) COMPLIES	PREPARED BY: <u>Milegh Patel</u>	DATE: <u>11/17/94</u>
() DOES NOT COMPLY	APPROVED BY: <u>Suzanne Patel</u>	DATE: <u>11/17/94</u>



RSD: NMT 6.0%

QC13-145c

Aide Pharmaceutical, Inc.

Page 2 of 2

LABORATORY TEST REPORT

FINISHED DRUG PRODUCT

PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USPCONTROL #: 4320ACHEMIST: K. K.VOLUME #: 325.01PAGE #: 177DATE: 11/12/97SAMPLE STAGE: over all complete

TEST	RESULT	LIMIT
DISSOLUTION: Media: 500mL 0.1N HCl Appar: I, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes	15 minutes: 1) <u>81.0</u> % 7) <u>80.8</u> % 2) <u>81.7</u> % 8) <u>80.0</u> % 3) <u>82.1</u> % 9) <u>77.5</u> % 4) <u>81.7</u> % 10) <u>85.6</u> % 5) <u>82.3</u> % 11) <u>81.5</u> % 6) <u>81.8</u> % 12) <u>84.6</u> % Average: <u>81.7</u> % 60 minutes: 1) <u>97.1</u> % 7) <u>100.5</u> % 2) <u>98.7</u> % 8) <u>98.2</u> % 3) <u>98.3</u> % 9) <u>93.4</u> % 4) <u>97.1</u> % 10) <u>101.8</u> % 5) <u>98.4</u> % 11) <u>96.5</u> % 6) <u>95.7</u> % 12) <u>99.5</u> % Average: <u>98.7</u> %	(Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual Tablet. (LC: Labeled amount)
<input checked="" type="checkbox"/> COMPLIES <input type="checkbox"/> DOES NOT COMPLY	PREPARED BY: <u>Mitchell Patel</u> DATE: <u>11/17/97</u> APPROVED BY: <u>Surya Patel</u> DATE: <u>11/12/97</u>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> APPROVED <u>W.S.A.</u> DATE <u>11/12/97</u> </div>

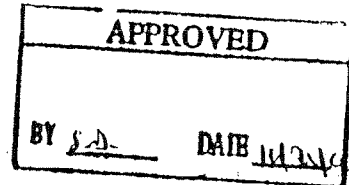
QC13-145d

Amide Pharmaceutical, Inc.

Page 1 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets 0.125 mgSPECIFICATION: USPCONTROL #: 4322 ACHEMIST: NP/PK VOLUME #: 1321-04 PAGE #: 1220 DATE: 11/21/94SAMPLE STAGE: Overall composite of Batch Dated 11/18/94

TEST	RESULT	LIMIT
DESCRIPTION: Color:	<u>Yellow</u>	Yellow
Profile:	<u>Round bisected tablets</u>	Round Bisected Tablets
Other: Debossed	<u>"A 145" on bisected side of the tablet</u>	"A 145" on bisected side of the tablet
THICKNESS: (Guideline)	<u>2.6</u>	2.0 mm to 3.0 mm
WEIGHT VARIATION:	<u>105.4 mg</u>	± 10% Theo. wt (105 mg) 94.5 mg - 115.5 mg
RIABILITY:	<u>0.1 %</u>	NMT 1.0 %
IDENTIFICATION: (A)	<u>The retention time at the major peak in the chromatogram of assay prep. corresponds to standard preparation.</u>	The retention time of the major peak in the chromatogram of assay preparation corresponds to standard preparation.
ASSAY: Digoxin, 0.125 mg	<u>100.8 %</u>	90.0% to 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity)	1) <u>100.1 %</u> 6) <u>98.5 %</u> 2) <u>99.4 %</u> 7) <u>97.8 %</u> 3) <u>98.9 %</u> 8) <u>97.9 %</u> 4) <u>99.6 %</u> 9) <u>98.4 %</u> 5) <u>100.5 %</u> 10) <u>97.8 %</u> AV: <u>99.1</u> RSD: <u>0.9 %</u>	85.0% to 115.0%
(<input checked="" type="checkbox"/>) COMPLIES	PREPARED BY: <u>Micah Pate</u>	DATE: <u>11/1/94</u>
() DOES NOT COMPLY	APPROVED BY: <u>Suzanne L. Pate</u>	DATE: <u>11/1/94</u>



RSD: NMT 6.0%

QC13-145c

Jc Pharmaceutical, Inc.

Page 2 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USPCONTROL #: 4322ACHEMIST: K.K. VOLUME #: 325.01 PAGE #: 204 DATE: 11/21/94SAMPLE STAGE: over all composite of batches

TEST	RESULT	LIMIT
DISSOLUTION: Media: 500mL 0.1N HCl Appar: I, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes	15 minutes: 1) <u>78.4</u> % 7) <u>84.3</u> % 2) <u>79.9</u> % 8) <u>83.9</u> % 3) <u>78.9</u> % 9) <u>80.3</u> % 4) <u>77.7</u> % 10) <u>82.5</u> % 5) <u>79.0</u> % 11) <u>81.4</u> % 6) <u>77.9</u> % 12) <u>81.0</u> % Average: <u>80.4</u> % 60 minutes: 1) <u>97.4</u> % 7) <u>98.2</u> % 2) <u>98.9</u> % 8) <u>98.4</u> % 3) <u>95.1</u> % 9) <u>95.0</u> % 4) <u>95.8</u> % 10) <u>95.7</u> % 5) <u>94.8</u> % 11) <u>99.2</u> % 6) <u>96.0</u> % 12) <u>93.6</u> % Average: <u>96.5</u> %	(Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual Tablet. (LC: Labeled amount)
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> APPROVED BY <u>S.A.</u> DATE <u>11/21/94</u> </div>	PREPARED BY: <u>K.K.</u> DATE: <u>11/1/94</u> APPROVED BY: <u>Sweyala</u> DATE: <u>11/1/94</u>	
<input checked="" type="checkbox"/> COMPLIES <input type="checkbox"/> DOES NOT COMPLY		

QC13-145d

PROTOCOL No. 001

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL

DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV. 00

BATCH SIZE: 1,600,000 TABLETS

PREPARED BY:

Anthony B. Bell

Regulatory Affairs Director

DATE:

11/2/94

APPROVED BY:

[Signature]

Manufacturing Operations Director

DATE:

11/3/94

[Signature]

Quality Assurance Director

DATE:

11/2/94

[Signature]

Quality Control Director

DATE:

11/2/94

[Signature]

Vice President Operations

DATE:

11-2-94

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV.00

PURPOSE:

This document provides the procedure to be followed to validate the manufacturing process for Digoxin Tablets 0.125 mg. It applies to the next three consecutive batches to be produced.

SCOPE:

This protocol is designed to be prospective in nature.

The guidelines presented here include all steps of the manufacturing process which may have an impact on product quality. They are as follows:

Raw Materials
Blending
Compression

Details of the process will be found in the completed copies of the Manufacturing Batch Records which are available in the file. A summary of the process is found on the attached flow chart. The major equipment used will be documented and monitored as described in the appropriate section below.

Temperature and humidity will be monitored in the production area on a daily basis.

2% excess of Digoxin is added in the finished product to compensate for production losses.

The data gathered during the course of this study will be evaluated and any adjustments to the predetermined specifications or guidelines will be made as warranted based on the results of the three validation batches.

PROCEDURE:

RAW MATERIALS

All raw materials used in a validation batch will be certified to meet all current Amide specifications for that item. These will specifically include particle size profile, bulk density, and tamped density.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
NPR NO. 14502 REV.00

Certification may be accomplished through direct testing by Amide, or an approved contract laboratory, or through a manufacturers Certificate of Analysis.

Digoxin, USP will be tested by Amide, or an approved contract laboratory for the complete monograph. This will include bulk density, tamped density, and particle size testing.

The excipients will be tested by Amide, or an approved contract laboratory, for those parameters required for expired stock retesting. In addition, particle size, bulk and tamped density will be run on all ingredients. The other results may be taken from the manufacturers COA.

In addition to the actual results, the name of the manufacturer, and the manufacturers lot number should be included in the report.

If more than one lot of a raw material is used in the production of the three batches the data should be evaluated to determine if any differences are detectable.

The acceptance criteria will be the specification limits for those tests listed in the Specification document.

BLENDING UNIFORMITY

The preblend will be produced in the 3 cu.ft. Twin Shell Blender, (#32). The speed will be monitored and documented both empty and during blending.

The blend in this step will be subjected to further processing, no sampling will be taken at this point.

The final blend will be produced in the 10 Cu Ft. Twin Shell Blender, (#35). The speed will be monitored and documented both empty and during blending.

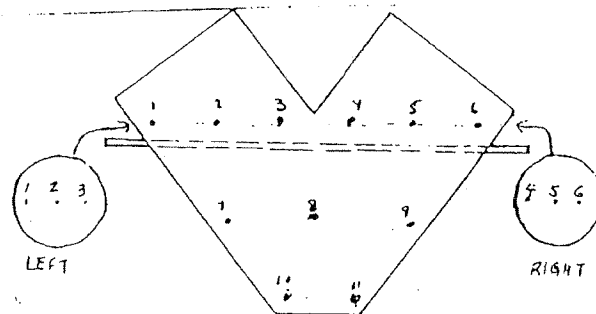
The sampling plan for the final blend is designed to evaluate overall blend uniformity, and those points in the blender where uniformity is most difficult to achieve. Samples are to be taken from the points shown below using only the 36 inch (small chamber) single port thief. The sample drawn should be about 315 mg which is three times the single dosage unit, and should be submitted to the laboratory in "Butter Paper."

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV.00

SAMPLING POINTS

- | | |
|------------------------------|--------------------|
| 1. Left Column - Top left | 7. Middle - Left |
| 2. Left Column - Top Center | 8. Middle - Center |
| 3. Left Column - Top Right | 9. Middle - Right |
| 4. Right Column - Top left | 10. Bottom - Left |
| 5. Right Column - Top Center | 11. Bottom - Right |
| 6. Right Column - Top Right | |



The samples are to be analyzed individually, without being ground, for Digoxin. No composite samples are to be prepared. The sample weight used for analysis should approximate 105 mg, which is the amount of this blend which would be present in one unit of the tablet.

Acceptance criteria is 85.0 - 115.0 % Th for the individual data points. This product has a 2% overage to compensate for the production losses.

Three sample of about 150 g will be taken with the help of a stainless steel ~~the~~ large chamber from the top center, ~~middle~~ center and bottom center of the blender. This sample will be tested for physical characterization which includes; bulk and tap density and particle size analysis. This data is for characterization only and these parameters will not be used to monitor routine production. Therefore, acceptance criteria will not be established.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14502 REV.00

COMPRESSION

Compression will be accomplished using the stokes 45 station tablet press. The speed will be determined and documented during the validation study.

During compression samples will be collected every 30 minutes hour by QA. These samples will be evaluated for individual tablet weight, thickness, and hardness. This will be 10 tablets for weight, and five each for thickness and hardness. Front and rear samples will be tested separately and will not be composited for any test in this section unless specifically stated.

The 30 minute samples should be arranged chronologically and the batch divided into thirds. Each third should be evaluated as described below for all tests except content uniformity. The samples for each test should be prepared by selecting, as close as possible, an equal number of tablets from each 30 minute sample. If selecting one tablet per hour results in a greater number of tablets than the test requires the distribution should be as even as possible.

TEST	N
Friability	10 g - 1 Run
Disintegration	6
Dissolution	12 (6 front & 6 rear)

Content Uniformity testing is to be run across the entire batch. One tablet per 30 minute sample is to be run with a minimum of 30 tablets being required. The tablets selected for testing should be weighed prior to testing and their identity maintained. If compression runs for less than 15 hours, the additional tablets should be selected as evenly distributed as possible throughout the batch.

A portion of the blend will be run at hardness of 0.5 - 2.0 KP and above 6.0 KP. This will determine the effect of hardness on friability and dissolution.

Minimum quantities sufficient to equilibrate the press will be run at both lower and higher speeds. The actual ranges will be determined during production. Samples will be evaluated for hardness and weight.

Data analysis will consist of Average and Standard Deviation, with comparison both within and across the three batches. The data collected within each batch will also be evaluated for any possible trends.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
NPR NO. 14502 REV.00

An overall composite sample will be prepared from all the 30 minute samples. This data will provide the basis for product release and will also be the initial data for stability.

Acceptance criteria will be as follows:

Target Weight (1 tablet):	105.0 mg
Target Weight (10 tablets):	1.050 g
Weight Range (1 tablet):	0.097 - 0.113 g
Thickness:	2.0 - 3.0 mm
Hardness:	1.0 - 6.0 KP
Friability	NMT 1%
Identification	Meets requirements.
Content Uniformity	85.0% - 115.0% (RSD NMT 6.0%)
Dissolution	Meets USP Requirement.
Assay	90.0 - 105.0%

AMIDE PHARMACEUTICAL, INC.

BATCH FLOW CHART FOR DIGOXIN TABLETS 0.125 mg
 BATCH SIZE: 1,600,000 TABLETS
 MPR # 14502, REV # 00

